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Collaborative Approach to Enable Engineering Team to Understand Real Needs of Customers

A Case Study in Medical Product Development

Helsinki Metropolia University of Applied Sciences

In the course of studying in Industrial Management Master's program, I have had great opportunity of working with bright minded people from whom I learnt a lifetime lesson.

I appreciate the support and cooperation from my colleagues, Mia, Esa, Virpi, Willem, Mikko, Sami, Jan, Pekka, Matti, Kristina, Santtu, Nora and many others.

I am also privileged to thank the staff at Metropolia faculty, especially Dr. Thomas Rohweder, Dr. Satu Teerikangas, Sonja Holappa, Zinaida Grabovskaia PhL, Dr. James Collins and Dr. Juha Haimala for their constructive support and flowless coordination.

My acknowledgment also extends to the students of Industrial Management Master's program with whom I have had enjoyable experience of learning and having fun.

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May 3, 2017

Author Title Number of Pages Date	Yonas Butta Collaborative Approach to Enable Engineering Team to Understand the Real Needs of Customers 55+ pages 03 May 2017
Degree	Master of Engineering
Degree Programme	Industrial Management
Instructors	Dr. Thomas Rohweder, Principal Lecturer Sonja Holappa, Senior Lecturer

This thesis focuses on one of the key challenges, understanding the real needs of customers, in a case company that provides patient monitors to hospitals and clinics to be used by health professionals such as doctors and nurses. Despite the complicated environment that these health professionals deal with, the case company's engineering team, responsible for developing the patient monitors lacks direct interaction with the health professionals. However, understanding the real needs of customers and addressing them, is the recipe of success for any offering. When it comes to medical products, this becomes even more than that due to the safety criticality of the industry.

The data inputs for this thesis were gathered from the company stakeholders for three purposes: to understand the existing practices (DATA 1), to co-create an initial proposal (DATA 2) and to shape the initial proposal and result in a final proposal (DATA 3). The outcome of this study indicates that a collaborative approach that involves the appropriate stakeholders and the usage of appropriate techniques at different stages of product development process is the key in the quest to identify and understand the details of customer needs.

The results of this study will help the case company, first, to understand the root causes for a varied set of customer needs. Secondly, it can help to focus the company's resources to what is relevant for customers. Thirdly, involving customers to understand their needs also helps to create good and lasting relationship with customers. Finally, transcending this practice throughout the company creates organizational culture which will ultimately create motivation and a sense of ownership in the employee's minds.

Keywords	Collaboration, Customer Needs

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1 Introduction

When products are developed, one of the main goals is to solve customers' problems and help the customers in accomplishing their jobs. This requires a good understanding of customer needs. Most importantly, it is vital to understand the environment customers deal with when designing a given product. When designing safety critical products, this becomes even more essential. The medical industry is one such example where a thorough understanding of customer needs is required. Indeed, these needs are the ones that dictate the ultimate product.

To understand customer needs, one of the key ingredients is to involve customers themselves in all stages of product development process, starting from the very beginning of setting strategy and roadmaps up until sales and after sales. This can be realized within a company by having the appropriate interaction and collaboration between customers and the respective departments such us marketing, sales, engineering, and so forth. Each department plays its own vital role in working with customers and understanding their true needs. What is even more vital is the interaction between customers and the engineering department as it is the engineering department that is responsible for designing the ultimate product. Of course, each department needs to collaborate seamlessly to work together for the same goal, understanding true customer needs.

In this study, a case company engineering team involvement is analyzed from the point of view of understanding customer needs. As it will be evident further in this study, the case company's engineering team, responsible for developing the final product, doesn't have enough direct contact with the end users, i.e. health professionals such as doctors and nurses. This prevents the team from thoroughly understanding customer needs and the end user environment, i.e. hospitals and clinics. With respect to this, this study discusses stakeholder roles and responsibilities towards understanding customer needs as well as the interaction among these stakeholders. The study further analyzes the strength and challenges identified within the case company in understanding customer needs especially by the engineering team.

The study further discusses the importance of involving customers in product development process. It also presents the various methods and techniques used to

identify and understand customer needs. Finally, this study proposes a solution co-created with the case company stakeholders to address the identified challenges.

1.1   Business Context

The case company for this study operates in the healthcare industry. One of the business unit of the case company, patient monitoring unit, is the focus of this study. The patient monitoring unit provides patient monitors along with related devices to be used in hospitals by health professionals (doctors, nurses for instance).

These patient monitors are used to convey critical information for the health professionals about a patient's conditions based on which important medical decisions for the patient are made. Examples of medical information that these patient monitors convey include patient's heart rate, blood pressure, oxygen level in blood and brain activity.

1.2   Business Challenge, Objective and Outcome

The customers' work environment (hospitals) often entails intensive care units, operating rooms and other facilities with patient monitors which are interlinked with other medical devices, systems, cables, etc. The case company's engineering team, responsible for developing the patient monitors, is not in direct contact with the health professionals who use these monitors. Instead, the engineering team receives information on customer needs through sales, product management and other channels. Besides, the engineering team lacks the appropriate level of exposure to the hospital environment where these monitors are used.

Such indirect contact between the engineering team and the health professionals in hospitals and clinics is bound to result in misinterpretation of the health professional's real needs. In other words, the products are not likely to be optimal in satisfying and addressing the true customer needs.

Accordingly, the objective of this thesis *is to develop a collaborative approach to enable the engineering team to better understand the real needs of the hospital personnel* who use these patient monitors.

The outcome of this thesis is a collaborative framework that can enable the engineering team to better understand the needs of the health professionals.

1.3   Thesis Outline

This case study was conducted by involving as many relevant stakeholders as possible in the case company. Data inputs were gathered from these stakeholders at various stages of this study. The first data input was collected to gain an understanding of the existing practices in the case company with an outcome of current strengths and weaknesses in the case company. The second data input was collected to co-create an initial proposal to address the identified weaknesses from the first data input. The final data input, feedback, was collected against the initial proposal to result in a final proposal. All the data inputs were gathered by having a one-on-one interview with each of the involved stakeholders.

The study is structured in the following manner. Firstly, the problem statement to which it is the focus of the rest of the study is clearly outlined at the beginning of this study. Secondly, to understand the current challenges as well as the current strengths in the case company, the existing practices towards understanding customer needs is discussed with key stakeholders. Thirdly, existing knowledge is consulted related to the identified challenges to base the foundation on which potential proposal is drafted. Fourthly, insights from the involved stakeholders is combined with the insights gained from literature to address the challenges and to come up with an initial proposal. Finally, the initial proposal is presented to stakeholders to validate the proposal and get valuable feedback to result in a final proposal.

This thesis is written in seven sections. Section 1 is the Introduction. Section 2 discusses the research design flow for this study. Section 3 explains the current practices in the case company towards understanding customer needs. It also presents the key strengths and challenges identified in the case company. Section 4 presents the relevant literature input to lay the foundation work upon which potential solution is proposed for the identified challenges in the case company. Section 5 discusses the initial proposal for the challenges identified in the case company by combining inputs from literature as well as inputs from the case company stake-

holders. Section 6 then presents the final proposal by considering inputs and feedback from the involved stakeholders on the initial proposal. Finally, Section 7 concludes the study by pointing out key takeaways from this study.

2 Method and Material

This section describes the research approach as well as the methods used for this study. It also presents the research design flow that shows the logical flow of this study. Furthermore, it explains the data collection process carried out in gathering different data inputs for this study.

2.1 Research Approach

According to Yin (2003), a case study involves an empirical inquiry especially when there is no clear understanding of that particular phenomena and its context (Yin 2003). Whereas in action research, the researcher begins investigating issues within some practical situation (Blichfeldt 2006). Despite the differences, Blichfeldt (2006), explains that both action research and case study research share commonalities between them. For instance, both try to get a deep understanding of a particular phenomenon in real life setting Blichfeldt (2006).

A qualitative case study explores a phenomenon within its context by using a number of data inputs from different point of views so that the phenomena is properly analyzed and understood (Baxter and Jack 2008). What is inherent to case study is the fact that the topic of interest is properly explored and analyzed. Besides, the importance of the phenomena is well revealed (Baxter and Jack 2008).

In order to effectively accomplish a case study, Yin (2003), suggests that the case should be bound, not broad and it needs to address one objective (Yin 2003). In other words, the case needs to be very focused and in a defined scope. Binding a case by time and place, by time and activity, by definition and context are some of the suggested ways to make a case to be focused and well scoped (Baxter and Jack 2008).

This thesis starts by defining a practical challenge in the case company in which the context is defined and known, to come up with a practical solution in the context of the case company. In that respect, qualitative case study best fits this scenario. The techniques used in the research include gathering of qualitative data using interviews and discussions with relevant stakeholders in the case company in different phases of this study. To gain a good understanding of the case, the stakeholders represent various roles and are experts in their respective roles.

2.2 Research Design of This Study

Figure 1 below shows the research design flow of this study.

Objective of the thesis:

To develop an approach to enable the case company's engineering team to understand the real needs of customers

DATA 1
One-
on-one
intervi
ews

Analysis of existing practices:

❑ Analysis of type and source of customer needs
❑ Analysis of flow of customer needs
❑ Analysis of current roles, responsibilities and interactions of internal stakeholders

Outcome
➕/➖ of existing practices

Best Practices from Literature:
❑ Key Stages in medical product development to Involve customers to understand their needs
❑ Techniques to understand customer needs

Outcome
CFW on understanding customer needs

DATA 2
One-on-
one in-
terviews

Initial Proposal Building:

Initial proposal development to enable engineering team to understand the real needs of customers.

Outcome
Initial Proposal

DATA 3
Present
aion/Dis
cussion

Validation of Proposal:

Discussion with stakeholders on the initial approach to enable engineering team to understand the real needs of customers.

Outcome
Final Proposal
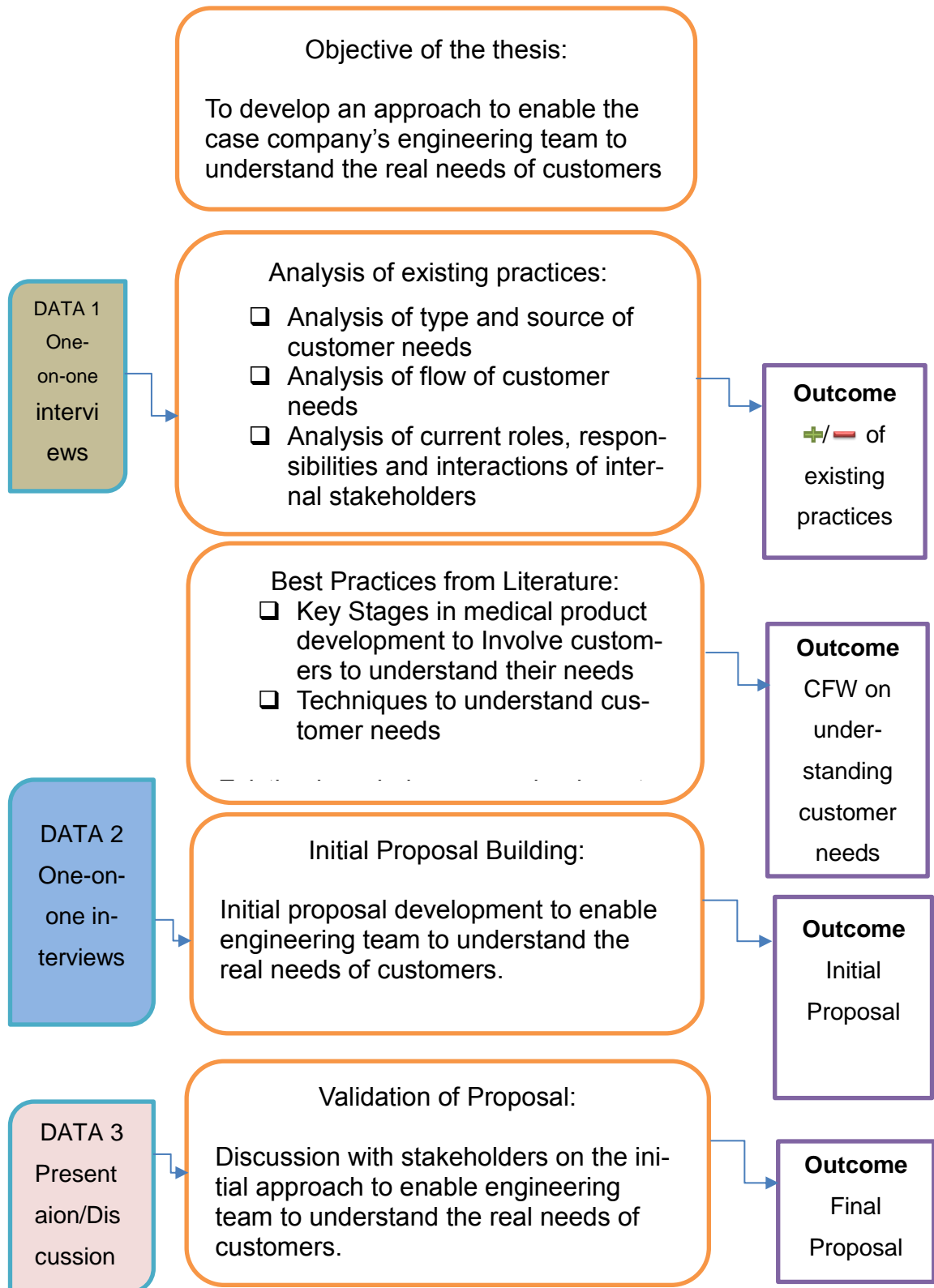
Figure 1. Research Design of this study.

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The main stages of this study are shown in orange boxes in the middle, starting from the Objective stage down until the validation stage. The outcome boxes on the right side of the figure show the outcomes at the various stages of this study.

As illustrated in the objective box, the objective of this study is to enable the case company's engineering team to understand the real needs of customers.

Secondly, the existing practices in the case company are identified by carrying out an analysis in three focus areas. Namely, the sources of customer needs, the flow of customer needs from customers down to engineering team and the current roles and responsibilities of stakeholders as well as the interactions among them. The outcome of the analysis on these three focus areas is shown as current strengths and weaknesses ("+" sign for strengths and "-" sign for weaknesses) in the outcome box as shown in Figure 1.

Thirdly, based on the results of the analysis, existing knowledge is consulted to address the weaknesses identified. For that, the key product development stages where customer involvement can happen as well as the potential best techniques that can be used at various stages of product development process to identify and understand customer needs are studied from existing literature. The outcome of this stage is a conceptual framework encompassing best practices in understanding customer needs

Fourthly, the strength identified by analysing the existing practices in the case company, best practices from literature and insights from the relevant stakeholders are used to come up with an initial proposal (as shown in the outcome box) to enable the engineering team to understand the real needs of customers.

Finally, feedback is collected on the initial proposal from key stakeholders to validate the proposal, resulting in the final proposal (as shown in the outcome box).

The data boxes, Data 1, Data 2 and Data 3 on the left side of the Figure are inputs from stakeholders at various stages of this study. Data 1, for instance, is an input used to analyse the existing practices in the case company. Data 2, on the other hand, is an input used to develop a co-created initial proposal. Finally, Data 3, used at the last stage of this research, is an input used to get feedback on the initial proposal and validate the final proposal.

2.3   Data Collection and Analysis

Data inputs for this study were gathered in three different stages for three different pur-poses.

The first data input, Data 1, for this study was collected by conducting one-on-one inter-views with key stakeholders as presented in the next sub-section. To clearly analyze the engineering team's involvement in understanding customer needs, it is equally beneficial to understand the roles and responsibilities of other teams that are also involved in the process of customer needs assessment. Hence, all the possible roles that are in one way or the other part of the process of understanding customer needs are considered in the study.

Table 1 below shows the summary of the data collection for this study. It lists the roles of the interviewees, the date, duration and type of each data.

Table 1. Overview of Data collection (Data 1, Data 2, Data 3) in this study.

	Position of the Interviewee	Date of Interview	Type of data collection	Duration of Interview
DATA 1				
1	Senior Clinical Specialist	21-March-2017	1-to-1 interview	75 minutes
2	Engineering Manager	22-March-2017	1-to-1 interview	85 minutes
3	Principal Engineer, Visualization and Usability	22-March-2017	1-to-1 interview	70 minutes
4	Software Architect	23-March-2017	1-to-1 interview	90 minutes
5	Marketing Manager	23-March-2017	1-to-1 interview	45 minutes
6	Senior System Designer	24-March-2017	1-to-1 interview	60 minutes
7	Global Product Manager	24-March-2017	1-to-1 interview	60 minutes
8	Global Product Manager	28-March-2017	1-to-1 interview	80 minutes

9	Program Manager	28-March-2017	1-to-1 interview	60 minutes
10	Senior Quality Manager	4-April-2017	1-to-1 interview	45 minutes
DATA 2				
11	Principal Engineer, Visualization and Usability	24-April-2017	1-to-1 interview	30 minutes
12	Engineering Manager	24-April-2017	1-to-1 interview	45 minutes
13	Product Manager	25-April-2017	1-to-1 interview	60 minutes
	Senior Clinical Specialist	25-April-2017	1-to-1 interview	45 minutes
DATA 3				
14	Engineering Manager	2-May-2017	1-to-1 discussion	30 minutes
15	Product Manager	2-May-2017	1-to-1 discussion	20 minutes
16	Senior Clinical Specialist	2-May-2017	1-to-1 discussion	30 minutes

Table 1. Overview of Data collection (Data 1, Data 2, Data 3) in this study.

As shown in Table 1, for Data 1 input, one-on-one interviews were carried out with key stakeholders within the case company. Interview notes were written down while each interview was conducted and a summary of each interview was drafted. As much as possible, extra care was taken to make sure that the interviewees' insights were properly summarized. For instance, in some cases, a summary of interviews was provided back to the interviewees to confirm that their messages were properly captured. In gathering Data 1, the themes of the interview questions were related to assessing the existing types and sources of customer needs, flow of customer needs from customers until the engineering team and defining the existing roles and responsibilities of stakeholders as well as their interactions.

Similarly, discussion on a one-on-one basis was conducted with stakeholders to gather Data 2, which will be used for co-creating the initial proposal. Finally, for collecting Data 3, the initial proposal was presented to the stakeholders and discussion on the initial proposal was made. The goal of Data 3 input is to get feedback on the initial proposal from the stakeholders.

In collecting Data 2, the goal and theme of the discussion was to get insights from stakeholders to co-create the initial proposal on the basis of conceptual framework formulated from literature. So, when DATA 2 was collected the conceptual framework was also presented to the stakeholders.

In collecting Data 3, the goal of the discussion was gathering feedback on the initial proposal. So, the initial proposal, which was co-created together with the stakeholders was presented to the selected stakeholders. Intentionally, one of the stakeholders who participated in Data 3 input was not part of the co-creation activity (for DATA 2 input) so that the feedback reflects different perspective.

In collecting all the data (Data 1, Data2, Data 3), the insights from the participating stakeholders were captured by taking notes during the interview/discussion session. However, in some cases, to confirm that the insights were captured properly, a summary of the interview notes were shown back to the interviewees.

The following section discusses the existing practices in the case company on three areas (Data 1): type and source of customer needs, how customer needs flow from customers to the engineering team and the different roles and their interactions in the case company towards understanding customer needs.

3   Analysis of Existing Practices in Understanding Customer Needs in the Case Company

This section discusses the existing practices in the case company towards understanding customer needs. Firstly, it gives a brief overview on how the analysis of the existing practices in the case company was carried out. Secondly, it discusses the type and flow of customer needs. Thirdly, it outlines the roles and responsibilities of relevant stakeholders as well as the interaction among them. Finally, it presents the strengths and weaknesses of the existing practices in understanding customer needs by the engineering team.

3.1   Overview of the Current State Analysis Stage

In order to analyze the existing practices in the case company, the following procedures were followed.

Fist, identification of potential stakeholders for the study was carried out with the help of three key stakeholders. This was done by discussing the overall idea of the study with these three stakeholders. After that, five more relevant stakeholders were identified and included. To have rich insight from different point of views, the stakeholders were selected so that each of them is an expert in their respective role and has a stake in the product development process. Example roles include product manager, engineering manager, clinical specialist, Usability and Visualization Principal Engineer and so forth.

Secondly, the themes of the interview with these stakeholders were prepared. Namely, type and source of customer needs, flow of customer needs from the health professionals to the engineering team and the roles, responsibilities and interactions of stakeholders in the case company with respect to customer needs.

Thirdly, a one-on-one interview session with each stakeholder on the selected themes was conducted. While conducting the interview, notes from the interviewees were jotted down. No voice recordings were used. However, after analyzing the interview notes, a summary of the interview was presented back to the interviewees to confirm whether the messages were properly captured.

3.2 Type and Source of Customer Needs

Broadly speaking, two types of customer needs were identified in the case company. The first type of customer need originates from the problems customers face in their daily routines. This type of need is very critical for customers in addressing their problems. Most of the customer needs fall into this category. In addition to actual problems, market is also one driver for customer needs. Customers request products or product features that they observe in the market. So, the market also influences customer needs. In other words, when customers look at similar products or product features in the market that they like, they request the case company to provide similar products or product features.

The second type of customer needs originates from complaint reports about product malfunction or some sort of technical issues. When the products do not work as expected, customers file a complaint about that issue. There is a possibility that such kind of unexpected behaviour would turn into a real customer need.

Depending on the type and source of customer need information, various roles are involved in receiving and analysing the needs. The following subsection presents the current roles and interactions among them in the case company towards understanding customer needs. Besides, it also explains the flow of customer needs information from customers to the engineering team.

3.3 Flow of Customer Needs Along with Analysis of Roles, Responsibilities and Interaction of Stakeholders

Figure 2 on the next page depicts a summary of the existing roles as well as the different level of interactions among these roles with respect to understanding customer needs. It also shows how customer needs flow from customers down to the engineering team. Although the Figure is a very simplified form, it gives a high level understanding of the existing roles and interaction in most of the cases.
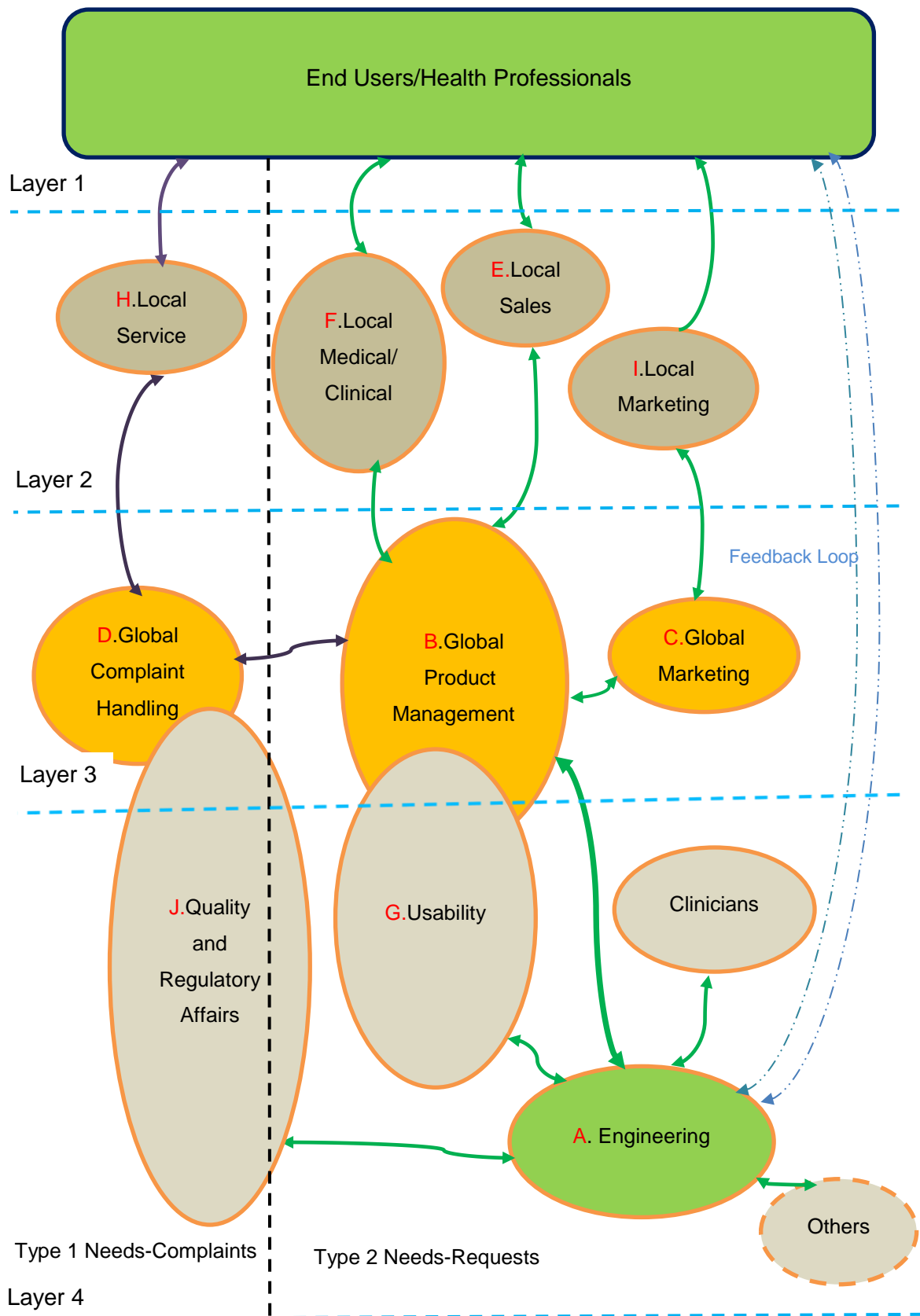
Figure 2. Flow of Customer Needs vs. the existing roles and their interactions.

As shown in Figure 2 (snapshot of which is shown below), the various roles are divided into layers, shown as blue dashed-lines, for the sake of simplicity as it helps to visualize the various roles and their interactions.

Customers/health professionals sit at the first layer, Layer 1. The closest roles to the health professionals, local sales, service, marketing and medical/clinical reside at the second layer, Layer 2. Complaint handling, global product management and marketing roles reside at third layer, Layer 3. Engineering team sits further down in Layer 4 and so forth. Some roles reside in more than one layer showing their interaction within and out of one layer. For instance, the usability role exists in both Layer 3 and Layer 4. When examining customer needs with product management role, the role resides at Layer 3 and when working with engineering team to further analyse the needs, it resides at Layer 4.

Similarly, the roles and interactions shown on the left side of the vertical black dashed-line deal with type 1 needs, needs that are driven by complaints. The roles and interactions on the right side of the black dashed-line deal with customer needs driven by actual problems customers face, type 2 needs.

As depicted in Figure 2, the first set of roles close to customers/end users are local sales, service, marketing and medical/clinical. These roles exist in almost each country in Europe where customers of the case company reside. For instance, there are dedicated local sales, marketing, medical/clinical and service teams in Finland.

The local sales team is responsible for providing technical training, performing sales activities and receiving end user needs. The local marketing team is responsible for performing marketing activities within the specific location (country). The local medical/clinical team is responsible for providing training mainly from the clinical applications point of view. The service team is responsible for receiving complaints, processing, analysing and addressing the complaints. In many cases, the service team addresses product malfunctions and technical issues raised by end users. However, as pointed out earlier, there are occasions when such complaints become real customer needs for which the complaint handling team works with product management team to further analyse the needs.

Upon receiving end user needs, the product management team then thoroughly examines the needs and presents it to the engineering team. Depending on the nature of the need, the product management team works with the usability team to better understand

the needs. When the product management team reaches the point where end user needs are properly understood, it shares the information with the engineering team after which a formal procedure to further analyse the needs continues within the engineering team. This typically involves the collaboration of the engineering team with other roles such as usability, quality and clinical to further analyse and understand the needs as shown in Layer 4 of Figure 2. These teams make sure that the customer needs are properly interpreted and analysed so that usability, quality and patient safety of the products will not be compromised when implementing the desired needs.

The following subsections provides a closer look at each of the existing roles with the focus on the role of the engineering and product management teams. Figure 2 helps to attribute the roles to the teams and their functions.

Figure 2. Flow of Customer Needs vs. the existing roles and their interactions.

A. Engineering

The engineering team, residing at layer 4 in the Figure, is responsible for realizing the needs of the end users (health professionals) into reality. For doing so, the team heavily relies on the information shared by the product management team. The product management team, one of the key teams in analysing the needs of the end users, plays a vital role in making sure that the end user needs are well understood before the information is shared with the engineering team.

Once the information is shared between the product management team and the engineering team, further discussion and analysis of the needs is conducted among the engineering, usability, clinical and quality team. This discussion session is the point at which the impact of the needs is assessed from several angles. For instance, the engineering team assesses the needs from implementation point of view whereas the clinical team assesses the needs from patient safety point of view.

Once the customer needs as well as their impact from different viewpoints is understood, the engineering team follows formal procedures to implement the needs into a product or product features. To make sure that the final implementation does indeed meet end user expectations, good feedback mechanisms exist shown as "feedback loop" in the Figure.

B. Global Product Management

The product management role, one of the key roles in the process, analyses and formulates the customer needs received from roles at layer 2 before sharing it to the engineering team. As indicated by the bold green line in Figure 2, the interface between this role and the engineering role is vital. The engineering role is entirely dependent on product management role about customer need information.

This role also closely cooperates with Global marketing role in the same layer. To make sure that customer needs are understood from usability point of view, the role also cooperates with usability role. In addition to analysing customer needs, this role is also responsible for scoping and prioritizing the various customer needs for implementation.

C. Global Marketing

The Global marketing role is responsible for accomplishing marketing activities such as preparing marketing materials and disseminating them to local marketing teams. Concerning customer needs, the role also participates in analysing customer needs information together with the product management role.

D. Complaint Handling

As the name indicates, this role is responsible for handling complaints and analysing them thoroughly. The team closely works with the product management team if a complaint turns into a real issue.

E. Local Sales

The local sales team is one of the roles that directly interfaces with customers. Every region (country) has its own dedicated sales team responsible for listening to the customer needs, performing sales activities as well as providing technical training to customers. When a need arises from customers, this team is responsible for conveying the need to the global product management team.

F. Medical/Clinical

The role of this team is mainly to analyse customer needs and the implications from the patient safety point of view. In other words, the purpose of this team is to act as the voice of customers by evaluating and analysing each need from the clinical practice view point.

G. Usability

This team is responsible for visualizing and analysing end user needs from the usability perspective. The team collaborates with the product management team as well as the engineering team in different level.

As usability is one of the corner stones in the design of medical products, it was observed that this team plays a paramount role in accomplishing usability activities in different phases of the product development process.

H. Local Service

As is the case with the local sales team, the local service team also directly interfaces with customers for complaint handling. In many cases, the customer complaints are re-lated to device malfunction or technical issues. However, there is also a possibility that a customer complaint requires product enhancement for which the complaint is for-warded to product management team for further analysis.

I. Local Marketing

This team also interfaces directly with customers and handles the marketing activities. The team also cooperates with the global marketing team. At times, end user needs might also be received through this team.

J. Quality and Regulatory Affairs

This team is responsible for providing insights from the regulatory and standards point of view, the aim of which is to avoid hazardous situations in the design of the patient monitors. This team works hand in hand with the complaint handling team as well as the engineering team to make sure that product quality is kept at a high standard and that patient risk is minimized.

3.4   Current Strengths of the Engineering Team Practices in Understanding Customer Needs

In general, there are several strengths in the existing processes concerning understand-ing of customer needs. For instance, the dedicated teams in every region, such as ded-icated local sales team and service team helps in listening to customer needs at a prox-imity. The role that the product management team plays in analysing customer needs, prioritizing the needs based on key criteria and presenting the needs in the way under-standable to the engineering team is also another good existing practice.

With respect to the engineering team as well, there are a few good mechanisms identified enabling the engineering team to understand customer needs. Firstly, although the customer need information is not directly received by the engineering team, the in-house multi-stakeholder discussion to make sure that customer needs are properly understood is one of the key strengths.

Secondly, the clinical and usability test during development and evaluation phases is another good strength in the existing practice. The usability test aims to avoid hazards resulting from possible use errors. In addition to that, such tests help to contribute to the effectiveness and efficiency of the patient monitors. On the other hand, the clinical tests aim to contribute to a safe design so that patient safety is addressed properly.

Thirdly, the feedback mechanism at later stages of the product development process to validate whether customer needs are properly translated into a product is another strength. For instance, it was observed that piloting a partially implemented product at some selected customer sites is found to be important to get valuable customer feedback. Another good example involves testing of the final product at a few selected customers' sites just before the product is launched to the market.

3.5   Current Weaknesses of the Engineering Team Practices in Understanding Customer Needs

Based on the data gathered and analysed, one of the weaknesses identified in the existing practice is related to the interaction of the engineering team with customers. As it was evident from the data, the team has minimal direct interaction with customers. This is caused by different factors. For instance, due to the nature of the environment the products are used, hospitals, concerns such as privacy prevents the engineering team for instance to easily visit the hospital environment to observe the usage of the products. Standards have also become more tighter and tighter for safety and privacy issues.

The other challenge is that the engineering team is dependent on other roles to get customer need information. Due to this, detailed customer need information might not reach the team. Of course, the product management team is "vital in translating the user needs and later sharing it with the engineering team" as pointed out by interviewees. However, work needs to be done in involving the engineering team at the very early stage when customer need is communicated.

Thirdly, although there is in-house multi-stake holder discussion to understand customer needs information, this was not found to be the silver bullet to validate and truly understand the background of customer needs. It was clearly pointed out by the interviewees that lack of robust mechanisms to properly validate the customer need information at an early stage is one of the existing challenge.

Finally, since the engineering team is mostly involved in implementing customer requests all the time, there is lack of mechanisms for the team to identify customer needs ahead of the customers themselves. In other words, this leaves minimal room for innovation. As pointed out by one of the interviewees, "it is way better to take a leap step instead of catching up what is in the market".

3.6   Summary of the Current Strengths and Weaknesses

To summarize, several good practices have been identified in the case company with respect to understanding customer needs. The dedicated teams residing close to customers to receive customer needs, multi-stake holder involvement to some extent in analysing customer needs and the feedback mechanisms at later stages to ensure customer needs is properly interpreted into products are among the key strengths.

On the other hand, the weaknesses identified in the existing practices and which will be the focus of this study are: the lack of direct interaction between the engineering team and customers especially at an early stage of customer need assessment, the dependency of the engineering team on other roles for customer need information, the lack of robust mechanism to scrutinize and truly understand the background of customer needs and the lack of mechanisms to identify customer needs ahead of customers themselves.

Figure 3 below shows the summary of the current strengths and weaknesses in the existing practices related to customer needs and their penetration to the engineering team in the case company.

Strength

- In-house multi-stakeholder discussion on customer needs to some extent

- In-house clinical/usability test

- Feedback mechanisms after implementation
  - Clinical evaluation
  - Feedback collection from some customer sites

Weakness

- Minimal direct interaction between the engineering team and customers

- Dependency of the engineering team on other roles for customer need information

- Lack of robust mechanisms to validate customer need information early in the product development process

- Lack of identiying and understanding customer needs ahead of customers themselves (Currently, mostly catching up)
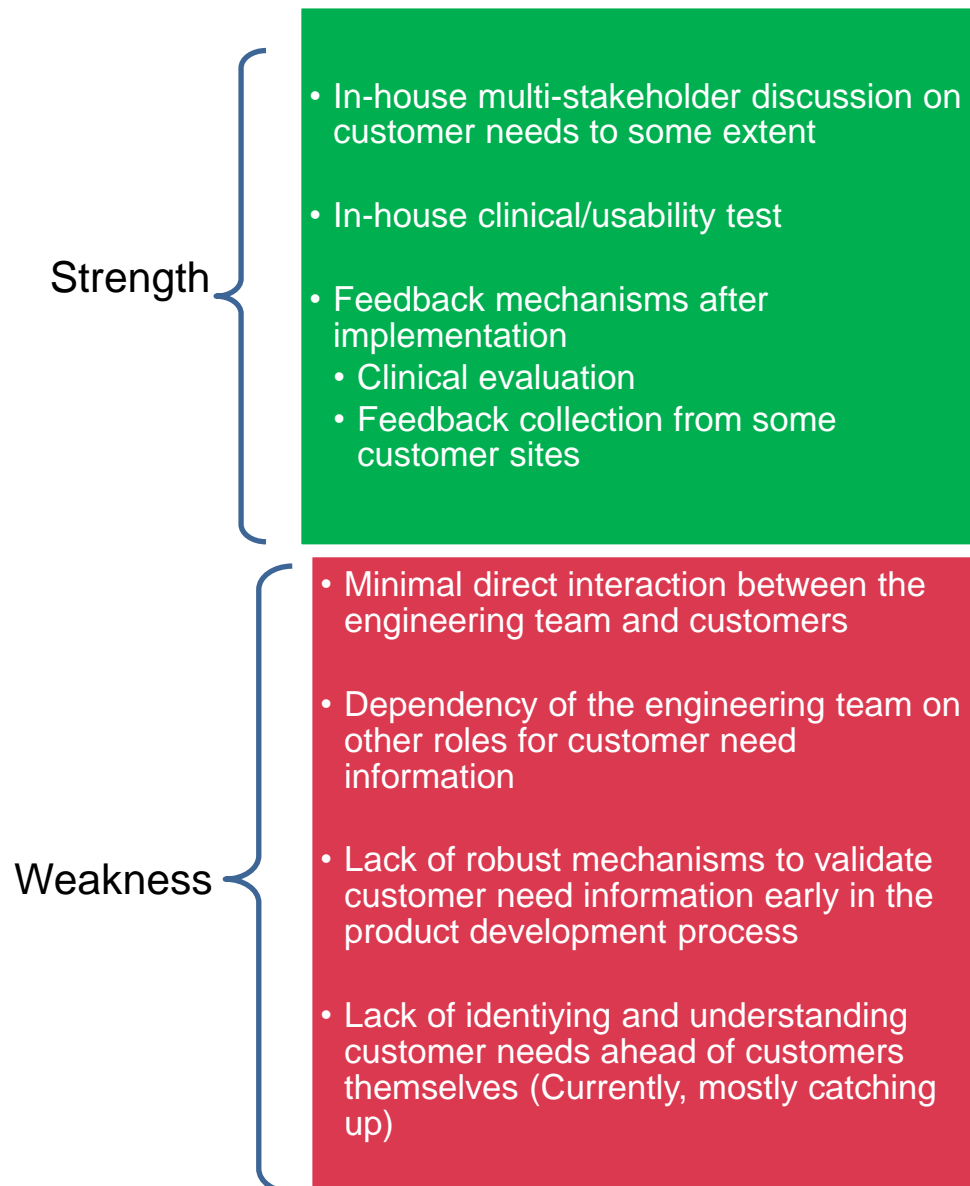
Figure 3. Strengths and weaknesses in the existing practices in the case company.

The subsequent sections of this study address these four challenges. The next section lays the ground for the proposal building how to improve the current practices by exploring best practice from existing knowledge and literature towards finding the mechanisms that can help in identifying and understanding customer needs.

4   Existing Knowledge in Understanding Customer Needs

Section three concluded with four interrelated challenges to be addressed in the case company. This section discusses mechanisms to address these challenges. It discusses the importance of involving customers and understanding their needs. It also discusses the key product development stages along with the techniques to identify and understand customer needs. It then presents a conceptual framework that combines the key product development stages and the relevant techniques used to identify and understand customer needs for this particular study.

4.1   Overview of Understanding Customer Needs

Deep understanding of customer needs is the most critical element and corner stone for any product development. It determines the success or failure of a product (Shah 2006). It consists of identifying, organizing and possibly quantifying what the needs of customers are with the goal of driving a requirement that is solution independent (Zhang 2011). Although from software development point of view, Saiedian (2000) also argues that, a deep understanding of customer needs is the basis for any requirement definition (Saiedian 2000).

Pointing to one of the key starting point to develop a product, Medina (Medina 2011), explains that new products are developed for different reasons such as to satisfy customer needs, to respond to competitions, to replace mature products or to gain competitive advantage and grow by creating completely new market. (Medina 2011). Although the drivers for product development vary, as long as a product does not meet customer needs, failure of the product is eminent.

When it comes to medical products development, due to the safety criticality of the industry, a deep and thorough understanding of customers and their needs, their workflows, their actual work environment, their skills etc. is more than a necessity (Shah 2006). On the other hand, lack of deep understanding of customer needs and their environment can lead to user errors which might result in sever hazards and even deaths.

However, identifying and understanding customer needs is not also an easy endeavor to accomplish. There are a number of challenges that needs to be addressed in order to

gain a good understanding of customer needs. This includes verbal and written communication among stakeholders including customers, resistance for change (for instance if products need to be changed when they mature), problem in articulating ideas/needs in a way understandable by many and organizational culture (Saiedian 2000).

In order to gain a deep understanding of customer needs, developing products with customers in mind is the key (Shah 2009).

4.2   Key Stages in Medical Product Development Process

Although there is some variation between the product development process of completely new products and product enhancements/modification process, both processes commonly possess fundamental stages (Rochford 1997).

Discussing on critical success factors in new product development in general, Cooper suggests multi-stage gate approach as one of the best practices for new product development (Cooper 2011). Figure 4 below depicts the concept. It shows key stages and the corresponding gates in each stage of the process.
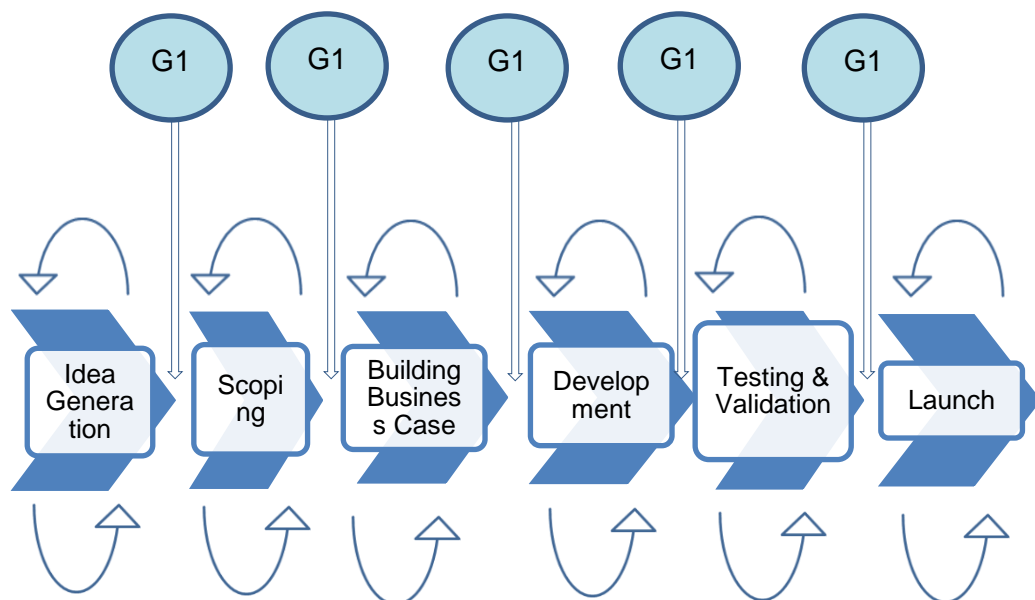

Figure 4. Stages in New Product development (Modified from Cooper 2011).

As shown in Figure 4, each stage is an iterative process by itself showing that early deliverables at each stage should be validated with customers to get feedback. At the end of each stage is a check point, a gate, that provides approval whether to proceed to the next stage or not.

In the first stage, idea generation and discovery, ideas and needs are assessed and discovered from different sources such as from customers, site visits, etc. (Cooper and Edgett, 2008). In the second stage, Scoping, preliminary market, technical and business assessment is carried out. At this stage, very little or no preliminary research is done. At stage three though, building business case, a detailed analysis of the market, business and customer needs is carried out, the result of which is a clearly defined product with clear business justification as well as clear action plan to follow (Shah 2006, Cooper and Edget 2008).

At stage four, development, the actual development of the product happens, the outcome of which is a prototype which is in-house tested and partially tested with customers. During testing and validation stage, the verification and validation of the product is carried out. It consists of activities such as field tests at customer sites and in-house in a simulated environment. It is also a stage where the business justification is confirmed to go to the next stage, launch stage. At the last stage, launch, the full commercialization and selling of the product happens. Besides, plans for post launch is implemented. (Cooper 2008)

From medical product development point of view, Shah et al. (2009) view the medical product development process as a five stage process: Stage one is the concept stage where ideas are generated and concept is developed, stage two is the design stage where devise design or re-design is carried out and prototype is developed, stage three consists of testing and trials of the prototype in-house and on the field, at stage four, production occurs based on business rational and at the final stage, deployment stage, the product is deployed in the market and feedback is gathered after deployment (Shah et al. 2009).

By combining the first two initial stages and leaving out the production and deployment stages set out by Shah et al. (2009), Craven et al. (2011) categorize medical device development process as a four-stage process. At stage one, user needs are identified and scoped together with users themselves, the result of which is an initial concept. At

stage two, validation and refinement of the concept is carried out to result in requirement document. Stage three involves the actual design phase of the product, prototype being an outcome. Finally, at stage four, evaluation of the product is carried out to verify that the product meets the set requirements. (Craven et al. 2011).

For this case study, the focus is not about the number of stages but rather it is about pointing out the key stages where customer involvement can potentially occur so that the appropriate techniques to identify and understand customer needs is applied. In that respect, the five stages deemed to be of high relevance are, initial concept development stage, requirement document development stage to formulate the initial concept, design stage where prototype is developed, evaluation stage (testing and trials of the prototype in-house and at the field) and deployment stage.

4.3   Customer Involvement

Many authors argue that involving customers in a product development process is vital and several benefits can be gleaned by involving customers such as increased access to valuable customer need information, uncovering of unmet needs, experiences and improvement ideas ultimately leading to better functionality and quality of products (Jones 1997), (Shah 2007) (Bridgelal 2008). When it comes to medical device development, involving customers is one of the crucial practice in addressing patient safety (Gosbee 2002).

When developing medical devices in particular, it is not only a question of choice but it is mandatory to involve customers at some level due to regulatory requirements such as FDA regulations in USA (Food and Drug Administration) and its equivalent in Europe, European Commission (EC) Medical Device Directive 93/42/EEC (Craven et al. 20011, Shah 2007).

Though regulation is one of the reasons that pushes medical product manufacturers to involve customers, the corner stone and the main driver behind involving customers in product development process is to obtain their needs and most importantly to understand them.

Despite the benefits it brings forth, involving customers is not also seen as an easy task to do. From an organization point of view for instance, there are concerns about confidentiality of sensitive company/product information, there are concerns about lack of resources, time and budget to name a few. Besides, cooperation and motivation of customers themselves is also another challenge. In other words, win-win situation should be created between a product development company and its customers (Shah 2007).

Putting aside the challenges to involve customers, a number of techniques can potentially be applied to the various stages of the product development process to involve customers in order to identify and understand their real needs. The following section discusses these techniques. Furthermore, the applicability of each technique to the various stages of the product development process is also analysed.

4.4 Techniques to Identify and Understand Customer Needs

There are several techniques used to identify and understand the details of customer needs. Although most of the techniques are best suited for new product development process, they are equally important in providing a detailed customer need information to improve/re-design an existing product as well. The following subsection discusses these techniques in general and their importance and applicability to this case study in particular.

4.4.1 Ethnography

Ethnography is one of the techniques used to study a customer in his/her environment. In this technique, the interaction of users with devices/systems, the interaction of users among each other, the user behaviours and the culture of the work environment, etc. are studied through open ended observation at the customer site for extended period of time (months or years) (Jones 1997, Martin 2006).

This technique helps to gain a detailed understanding of the customer environment which helps to develop the right solution that is relevant for the environment being studied. It also helps to discover needs customers themselves are unaware of. From medical devices point of view as well, Martin (2006) points out that this method has the potential to uncover unmet or poorly met needs and helps to gain contextual customer need information (Martin 2006).

Although the length of observation is not specifically pointed out, the importance of observing customers at their environment for identifying and understanding customer needs is also well explained by Leonard (1997) (Leonard, 1997). Leonard (1997) argues that a number of benefits can be gained by observing customers at their environment such as identifying unarticulated needs, needs that customers themselves are unaware of, identifying work-arounds (customization of existing products) by the users to fit for their purpose and learning customers' environment. (Leonard 1997).

On the down side, this technique is resource intensive and as a result it is expensive as it requires observation of the customer environment for a longer period of time.

4.4.2   Contextual Inquiry

Similar to ethnography, the key to contextual inquiry technique is also observation. The customer environment is studied for a short period of time with predetermined goal in mind. This technique provides contextual customer need information where existing solution hasn't met. It involves asking customers the "why" question while customers accomplish their tasks or it can be done after customers accomplished their tasks. This technique, at its core, involves focused and critical observation (Jones 1997, Martin 2006).

Besides observation, this technique also involves a one-to-one interview with customers in order to develop a shared interpretation of the observation (Beyer and Holtzplatt 1999). Beyer and Hotzplatt further stress that all stakeholders involved in the product development process should participate in observing/interviewing customers at the customers' environment (Beyer and Holtzplatt 1999).

After conducting the observation/interview at the customer sites, the data is further analysed and interpreted in a cross-functional team to come to a shared interpretation and understanding of the needs of the customers.

Compared to ethnography, contextual inquiry is less resource and time consuming but at the same time, it provides rich contextual customer need information. However, since this technique involves asking questions while customers accomplish their tasks, it might be intrusive.

4.4.3 Focus Groups/Interview

The purpose of this technique is also to get contextual customer need information using a discussion group that involves a few number of users (between eight and ten) (Martin 2006) (Craven et al. 2011). This technique is relatively less time and resource intensive and helps to uncover emotional and cultural aspects towards a product/system as well as organizational issues of the customer environment. On the other hand, it is likely that individual users may not freely discuss issues in a group setting. Hence, it is advisable to couple this technique with some other techniques such as observation (Jones 1997, Martin 2006).

4.4.4 Cognitive Walkthrough/ Being a User

By allowing the product development team to act as users of the product, needs that customers themselves might not be able to articulate can be identified. (Jones 1997, Martin 2006). In this technique, once tasks a customer accomplishes are identified, an expert (usability specialists for instance) then can play the role of the customer and cognitively "walks through" the customer experience (Jones 1997). Hedge (2013) also agrees that this technique can help in evaluating the performance of a sequence of pre-defined tasks by going through customer requirements in a structured manner (Hegde 2013).

Since this technique doesn't require the involvement of customers and can be done in-house, it is relatively easy and very cheap to carry out. However, it requires good understanding of the actual users and their requirement (Martin 2006).

As pointed out by Jones (1997) and Martin (2006), besides identifying needs that customers may not articulate themselves, this technique helps to identify usability issues and how easy a device/system is for a user (Jones 1997, Martin 2006).

4.4.5 Usability Tests

Regulatory requirement set by regulatory bodies such as FDA (Food and Drug Administration) in US and the equivalent bodies in Europe and elsewhere recommend medical

device manufacturers to incorporate usability tests in the product development process for a safe design (Hegde 2013, Martin 2006). The main driver for such standards is associated with a number of reported deaths and severe incidents resulting from poor usability of medical devices (Boakes et al., 2008).

According to Hedge (2013), usability encompasses the testing of a product model, prototype or production unit to assess the ease of use, efficiency of use, ease of learning, ease of remembering and user appeal (Hegde 2013).

With respect to the product development stages, Hedge (2013) suggests that usability test can be used either early in the product development stage to refine designs iteratively or at later stages to validate whether a product meets usability objectives set forth priori (Hegde 2013). However, Martin (2006) suggests that usability tests should be used throughout the product development process (Martin 2006).

Martin (2006) also agrees that appropriate tasks as well as context of use needs to be specified to effectively get a valid outcome out of usability tests (Martin 2006). He further proposes that the testing can be carried out either by the actual users or by experts (for instance usability specialists and clinicians). As a result, the testing environment can be a laboratory setting, simulated environment or the actual customer environment. (Martin 2006, Hegde 2013). Martin (2006) also stresses that observing users testing a given device reveals problems that might not be noticeable by the users themselves but easily noticeable by observers (Martin 2006).
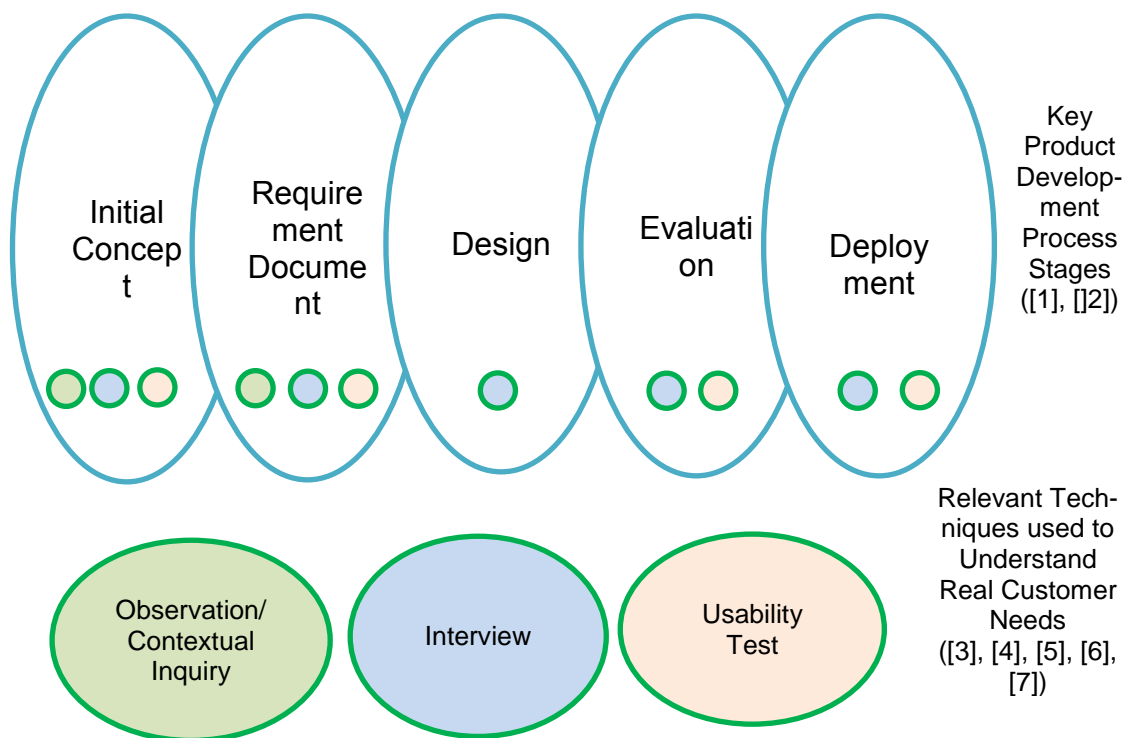
Usability tests are powerful in revealing quantitative data as well. For instance, the time it takes to accomplish a certain task or number of errors in accomplishing a certain task can be analysed (Martin 2006).

From business stand point, a number of advantages can be gained from usability tests especially early in the product development process, Hedge (2013) points out. They are "faster time to market (by avoiding user interface problems late in the development cycle); simpler user manuals and related learning tools; improved marketing through credible claims about a device's usability and associated gains in user productivity; increased sales (attributable to enhanced user interface quality; reduced customer training and support requirements; extended market life; clearer compliance with regulatory requirements; reduced exposure to liability claims; and increased user satisfaction." (Hegde 2013, p 1).

4.5   Conceptual Framework to Understand Customer Needs

The foundation to develop the conceptual framework for this study is based on customer involvement. According to literature study, involving customers in the product development process is the first step in the quest to identify and understand customers and their needs. Following that, determining the key stages to involve customers as well as the associated techniques to identify and understand their needs is the second logical step.

Figure 4 illustrates the conceptual framework for this study. It combines two main elements. The key stages in medical product development process to involve customers (shown as blue elliptical circles) and the relevant techniques that can be used to identify and understand customer needs at the various stages (shown as green elliptical circles).

Initial Concept | Requirement Document | Design | Evaluation | Deployment — Key Product Development Process Stages ([1], []2])

Relevant Techniques used to Understand Real Customer Needs ([3], [4], [5], [6], [7])

Observation/Contextual Inquiry | Interview | Usability Test

Sources:
1.Craven et.al. (2011), The role of the user within…
2.Shah et al. (2009), Developing Medical Device...
3.Jones, D. (1997), The Journal of Product Innovation...
4.Martin J.L. (2006), Capturing User Requirement

5.Beyer and Holtzplatt (1999), Contextual…
6.Hedge, D. (2013), Role of Human Factors…
7. Leonard, D. (1997) Spark innovation…

Figure 4. Conceptual framework for identifying and understanding customer needs

As shown in Figure 4, the framework also shows mapping of the techniques to the key stages of the product development process (shown in small green circles inside of the blue elliptical circles). For instance, observation/contextual inquiry, interview and usability tests are found to be of high importance to identify and understand customer needs in the early two key stages, namely initial concept and requirement document development stages.

As shown in Figure 4, the key product development stages deemed to be important to involve customers to understand their needs are the initial concept stage, requirement document development stage, design stage, evaluation stage and deployment stage. The potential techniques used to identify and understand customer needs as suggested by literature and found to be relevant for the case at hand are observation, contextual inquiry, interview and usability tests.

The first stage, initial concept development stage, is where the very customer need information is gathered and analysed. In terms of identifying and understanding customer needs, this stage is a key (Zhang 2011). Because, the better the customer needs are understood at this early stage, the less costly and the easier the subsequent product development processes will be.

All the proposed techniques, goal oriented observation, contextual inquiry, interview and usability tests can be used to identify and understand customer needs at this stage (shown as small green circles inside the blue elliptical circles). Conducting contextual inquiry/goal oriented observation on customer sites and coupling the observation with interviews helps to confirm the customer need data gathered from observation. From such kind of observation, a number of information can be gleaned such as usability issues that customers face, how customers solve their problems by creating work arounds that the existing products do not solve, how their current work flows look like and most importantly needs that customers might not be aware of themselves.

Secondly, at stage two where requirement document is developed, all the three techniques are still useful to translate the needs into a meaningful specification and to confirm that the needs are properly translated (Saiedian 2000). From practicality point of view, the two initial stages can go hand in hand iteratively until the needs are fine tuned to result in a requirement document.

Thirdly, at stage three, where the actual design takes place, periodic interview with customers might be sufficient to communicate the design at a reasonable interval during the development phase.

Fourthly, stage four constitutes activities to evaluate and validate whether customer needs are properly translated into the products. At this stage, various testing activities are carried out both in-house as well as at customer sites. usability test together with interview constitute the best techniques to be used at this stage.

Finally, at the deployment stage, customer feedback from the market is gathered and this can be done by conducting usability tests on customer sites and/or conducting interviews with customers.

To summarize, involving customers at various stages of product development process is the key to identify and understand their needs. The key medical product development stages that are of high relevance to involve customers are initial concept development stage, requirement document development stage, design stage, evaluation stage and deployment stage. The corresponding techniques that can be used to understand the details of customer needs relevant for this study are contextual inquiry, goal oriented observation, interview and usability test.

The next section, section five, builds the initial proposal on the grounds of the above conceptual framework to address the key weaknesses of the case company identified in section three.

5   Initial Proposal to Enable the Case Company's Engineering Team to Understand the Real Needs of Customers

This section combines existing best practices used in the case company with the relevant insights gained from literature as well as insights from the stakeholders in the case company to co-create an initial proposal that can potentially address the challenges identified earlier.

5.1   Overview of Proposal Building Stage

In Section 3 of this study, the existing practices identified from literature towards understanding customer needs were discussed including the key current strengths as well as weaknesses.

Section 4 on the other hand presented the different techniques that can be used to identify and understand customers and their needs by involving customers themselves at various stages of the product development process.

In this Section 5, the initial proposal was built in the following manner. Firstly, the key findings of the existing practices based on DATA 1 as well as the conceptual framework to base the initial proposal building was presented to the stakeholders on a one-on-one basis.

Secondly, taking the conceptual framework as a foundation and the existing strengths in the case company, inputs to address the weakness areas were gathered from each stakeholder. For this study, four stakeholders participated in building the initial proposal. The proposal was built in such a way that the insights from the first stakeholder are already incorporated in the initial proposal before conducting the co-creation activity with the second stakeholder. Similarly, the insights from the second stakeholder are incorporated in the initial proposal before conducting the co-creation activity with the third stakeholder and so forth.

Finally, the initial version of the proposal, built on the basis of the conceptual framework as well as the various insights from the stakeholders was built.

5.2   Key Strengths and Challenges from the Existing Practice in the Case Company

As it was point out earlier in section three, the in-house multi-stakeholder discussion to understand customer needs, usability and clinical activities as well as the feedback mechanisms at the later stages of product development process are some of the key strengths in the current practice within the case company.

On the other hand, the lack of direct interaction between the engineering team and customers at an early stage of customer need assessment, the dependency of the engineering team on other roles for customer need information, the lack of robust mechanism to scrutinize and truly understand the background of customer needs and the lack of mechanisms to identify customer needs ahead of customers themselves were found to be the challenges in the case company.

5.3   Insights from Stakeholders

Table 2 below summarizes the insights gathered from the stakeholders. The table shows the identified challenges in the case company and the corresponding insights from the stakeholders to address each challenge.

Table 2. Insights from the stakeholders for proposal building.

	Challenges	Insights from Stakeholders
1	**Lack of direct interaction between the engineering team and the health professionals**	Periodical visits to customer sites, and improved involvement of the health professionals in the product development process can solve this challenge.
2	**The dependency of the engineering team on other roles for customer need information**	Two different insights were reflected on this challenge. On the one hand, most of the stakeholders agree that the engineering team should involve in assessing and understanding the needs as early as possible. On the other hand, though, one stakeholder suggested that it is a better approach for other roles (product management and sales in this case) to handle the customer need assessment and

		forward it to the engineering team in a language understandable by the engineering team.
3	**Lack of mechanisms to scrutinize the background of customer needs**	Spending more time and involving the relevant roles early in the product development process in analysing and understanding of the background of customer needs was the suggested solution. Cross team collaboration among different roles. Quick prototyping and validating customer needs was also suggested.
4	**Lack of anticipating customer needs ahead of Customers themselves**	As one stakeholder puts it, "it is way better to take a leap step instead of catching up what is in the market". Other stakeholders also agree that a thorough understanding of the customer environment is the enabler to anticipate customer needs ahead of themselves and to come up with a product that will solve not only the current problems/needs but also the future problems/needs. Observing customers at their actual work environment accomplishing their daily activities is a key to identify current customer pain points and potential future needs. This can ultimately imply either improvement in existing product or designing a completely game changer product.

As seen from Table 2, it summarizes the insights from the stakeholders for handling the identified challenges in the case company, and shows the corresponding suggestions from the stakeholders to address each challenge.

5.4   Insights from Literature in Understanding Customer Needs

As pointed out earlier in Section 4, customer involvement is the key to obtain and understand their needs. Various techniques to identify and understand customer needs were

also presented in section four. Among the techniques, contextual inquiry, observation, interview with customers and extensive usability tests are the relevant techniques that can possibly address the current challenges in the case company.

The first and most important technique that can help to address the challenges in the case company is observation. As pointed out in the business challenge, the complexity of the customers' environment where the patient monitors are being used puts the importance of this technique at the top. Using this technique in the early stages of the product development process also addresses most of the identified challenges. By properly setting up a multidisciplinary team and organizing a goal-oriented observation of customer environment, the fruit from this technique can be harvested.

The second most important and relevant technique that can be used to identify and understand the needs of customers for this study is contextual inquiry. This technique also shares similar features as observation but it involves inquiring customers the "why" question while they are accomplishing their jobs. By taking a good care not to interrupt the routines of the end users, this technique can also reveal a detailed contextual customer need information about the work flows of customers.

Interview is also another key technique that can be coupled with observation and/or contextual inquiry to clarify and glue the customer need information that is obtained using those techniques.

The other vital technique that is already in use in the case company but can also be improved somehow is usability test. By conducting extensive usability test at various stages of the product development process, a good understanding of customer needs can be gained. Usability tests also provide information on how efficiently, effectively and safely the health professionals can accomplish their tasks.

Based on literature, no single technique provides the full set of customer need information. Thus, the above four relevant techniques can at least be used in order to address the challenges in the case company.

5.5   Initial Proposal to Enable the Engineering Team to Understand the Real Needs of Customers

Figure 5 below illustrates the initial proposal which is built on a collaborative mechanism to address the identified challenges in the case company.

The three core elements depicted in the figure are: (a) the key product development process stages that customer involvement can happen (shown in blue-lined elliptical circles), (b) the potential techniques used to identify and understand customer needs (shown as green-lined elliptical circles) and (c) the relevant stakeholders that can be involved in the quest to understand customer needs (shown as black-lined rectangles). It also shows what technique to use, when to use each technique, what roles to involve and when to involve each role.
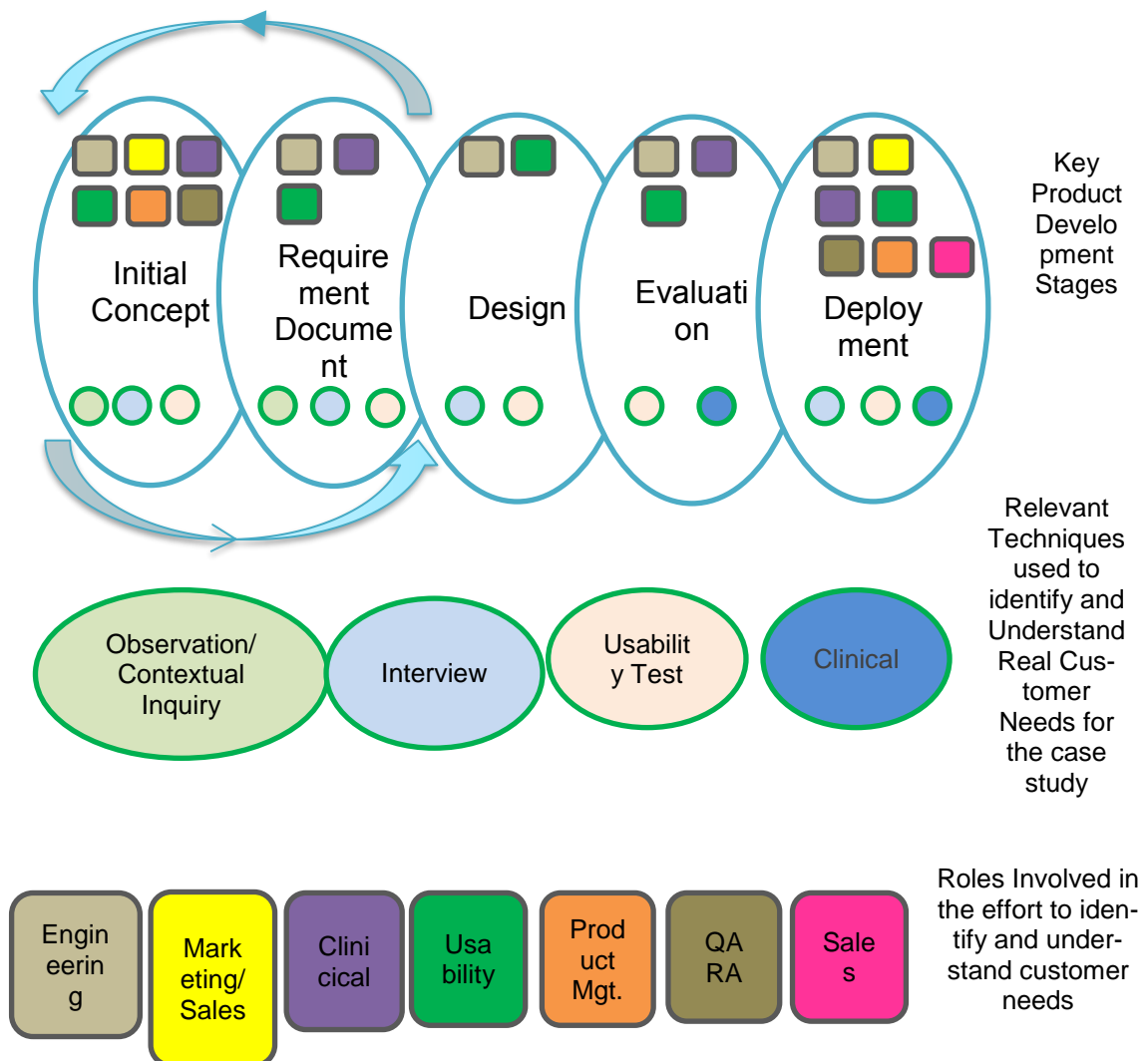
Figure 5. Initial proposal for the Collaborative approach to understand the real needs of customers in the case company.

As seen from Figure 5, most of the challenges identified in the case company can potentially be addressed by focusing in the first two key stages, initial concept development and requirement document development stages. The potential techniques used to identify and understand customer needs as suggested by literature and found to be relevant for the case at hand are observation, contextual inquiry, interview and usability tests. However, clinical test is one additional technique that is in use by the case company (one of the key strength identified in section three).

At stage one, all the four techniques, goal oriented observation, contextual inquiry, interview and usability tests are proposed to be used to identify and understand customer needs (shown as small green circles inside the blue elliptical circles). Contextual inquiry as well as observation require multi-disciplinary team involvement in order to gather observational data from different points of views. Hence, engineering, usability, clinical, product management, marketing/sales and quality and regulatory affairs (QARA) roles are found to be the relevant stakeholders that can participate when conducting the observation/interview (shown in black-lined small rectangles) at the initial concept stage.

Secondly, at stage two all the three techniques are still useful for the case at hand to translate the needs into a meaningful specification and to confirm that the needs are properly translated. From stakeholder involvement point of view, engineering, clinical and usability team would be the best fit to formulate the requirement document. Referring to one of the challenges identified in the case company, this stage is vital in validating the assumptions about customer needs and thoroughly understanding the needs.

Thirdly, at stage three, interview together with usability test are the proposed techniques for the case company. It can be argued whom to involve at this stage but the engineering team and usability team are most likely the best candidates. The engineering team is the one responsible for the actual design and can cooperate with usability team especially in user interface design activities.

At stage four, various testing activities are carried out both in-house as well as at customer sites in the case company. Clinical and usability tests constitute the best techniques to be used at this stage on top of the various in-house tests. Engineering, usability and clinical teams are the best candidates to participate at this stage.

At this stage, the existing clinical and usability test activities within the case company are worth mentioning. Pilot testing on some customer sites, extensive in-house testing, as well as limited-release test on some customer sites just before the launch of the final

Finally, at the deployment stage, usability test, clinical test and interviews are proposed techniques. Many stakeholders can be involved at this stage, engineering, marketing/sales, clinical, usability, product management, quality and regulatory affairs as well as service.

To summarize, the challenges identified in the case company are: the lack of direct interaction between the engineering team and customers, the dependency of the engineering team on other roles for customer need information, the lack of robust mechanism to scrutinize and truly understand the background of customer needs and the lack of mechanisms to identify customer needs ahead of customers themselves.

To address these challenges, this section proposed a collaborative approach involving what technique to use (goal oriented observation, contextual inquiry, interview, usability and clinical evaluation) to understand the nitty gritty details of customer needs, when to use each technique (initial concept stage, requirement document development stage, design stage, evaluation stage, deployment stage), what roles to involve (engineering, marketing/sales, clinical, usability, product management, quality and regulatory affairs, service) and when to involve each role (initial concept stage, requirement document development stage, design stage, evaluation stage, deployment stage).

The following Section 6 validates the initial proposal through discussions with key stakeholders in the case company.

# 6   Validation of the Proposal

This section presents the feedback gathered (shown as Data 3 in the research design flow in section two of this study) in an effort to validate the initial proposal presented in section five.

6.1   Overview of Validation Stage

The validation of the co-created initial proposal for this study was conducted by having a one-on-one discussion with three key stakeholders. To get a bit of different perspective, one of the stakeholders was not part of the initial proposal building. First, the discussion was held with this stakeholder who was not part of the initial proposal building. Secondly, the initial proposal as well as the feedback from the first stakeholder was presented to the other two stakeholders. Two valuable feedback were collected and presented as follows.

6.2   Feedback from Stakeholders on the Initial Proposal (Data 3)

Upon discussing the initial proposal with the key stakeholders, two key feedback were noted. The first feedback is related to extension of the iteration cycle beyond the first two stages of the product development process. In the initial proposal, the iteration of the process was limited to the first two stages of the product development process as shown in the snapshot of the initial proposal below.
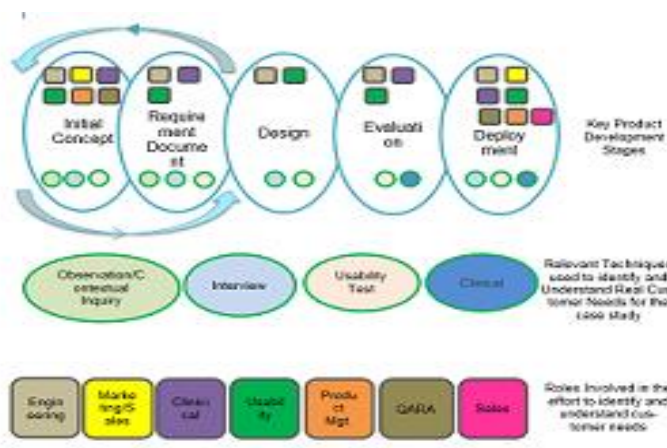
Snapshot of Figure 5 (Initial Proposal).

It means that the iteration should go up until Evaluation stage. In essence, by having a quick prototype and confirming whether the customer needs are properly translated in the prototype guarantees that the needs of customers are properly understood.

The second valuable feedback gained from stakeholders on the initial proposal is about the involvement of roles. As shown in the snapshot of the initial proposal, the product management role (orange rectangle in the figure) is not involved in the requirement document development stage. According to the feedback though, the product management role should also participate in the requirement document development stage. Since the product development role has already good level of interaction with customers and an understanding of their workflow, involving the role in the requirement document development stage will help leverage such valuable expertise.

6.3   Summary of the Final Proposal

Figure 6 below shows the final proposal incorporating the feedback on the initial proposal. Based on the feedback, the components in the figure which have slanted green line are the additional components on top of the initial proposal.
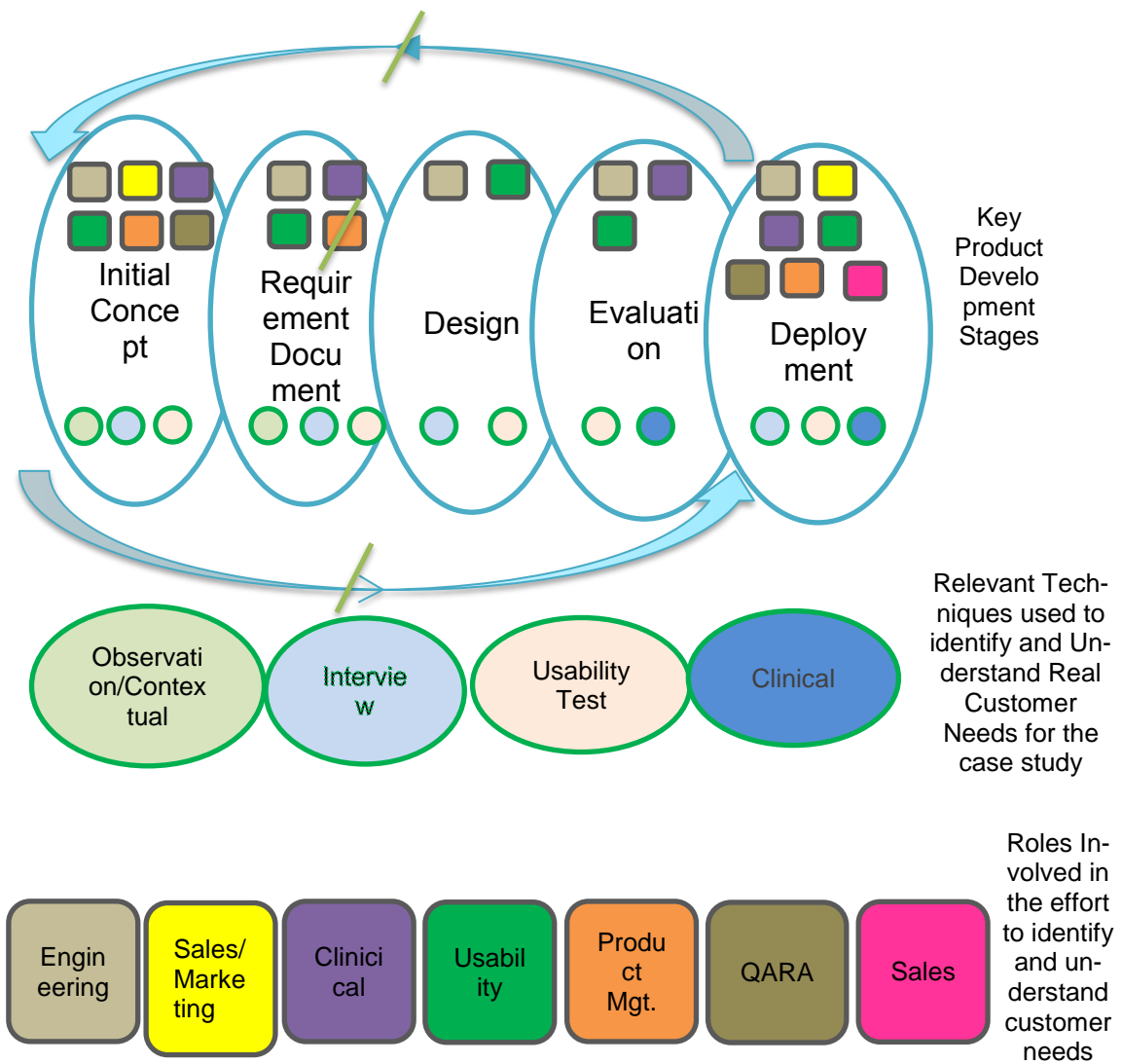
Figure 6. Final proposal for the Collaborative approach to enable engineering team to understand the real needs of customers.

The first valuable feedback, the extension of the iteration cycle beyond the first two key product development stages up until evaluation phase, is shown by the blue arrows in the figure.

The other feedback, related to the involvement of product development role, is shown by the orange rectangular small box inside the second key stage of the product development process, requirement development stage.

7 Conclusions

This section contains a brief summary of this study as well as some of the managerial implications on how to implement the proposed solution. It also discusses the four criteria upon which this thesis is evaluated.

7.1 Executive Summary

The goal of this thesis was to device a mechanism to enable the case company's engineering team to understand the real needs of the customers. The case company for this study provides patient monitors for hospitals and clinics to be used by health professionals such as doctors and nurses. The customers' environment in which these patient monitors are used is heterogeneous and complex in nature containing other medical devices, systems, etc. that are interlinked with these monitors. However, the engineering team, responsible for the design and development of these monitors, lacks direct interaction with the health professionals operating these patient monitors. This is likely to result in misunderstanding of the real needs of the health professionals by the engineering team and might lead to a sub optimal product.

The data inputs for this thesis were gathered from the company stakeholders for three purposes: to understand the existing practices in the case company (Data 1), to co-create an initial proposal (Data 2) together with the case company's stakeholders and to shape the initial proposal and result in a final proposal (Data 3).

Based on the findings from Data 1, existing good practices to understand the needs of customers were identified in the case company. This includes in-house stakeholder discussions on customer needs, good clinical and usability practices and feedback mechanisms at later stages in the product development process. On the other hand, four interrelated challenges were identified in the case company. Namely, the lack of direct interaction between the engineering team and the health professionals, the dependency of the engineering team on other roles for customer need information, the lack of robust mechanism to scrutinize and truly understand the background of customer needs and the lack of mechanisms to identify customer needs ahead of customers themselves.

These challenges necessitate better customer involvement in the product development process. To that end, the key product development stages (initial concept development

stage, requirement document development stage, design stage, evaluation state and deployment stage) to involve customers as well as potential techniques (goal oriented observation/contextual inquiry, interview and usability test) that can be used to identify and understand the real needs of customers at these key stages were identified from existing literature. A conceptual framework was then built based on these two concepts: the key product development stages where customer involvement can happen and the relevant techniques used to identify and understand their needs at each stage.

Accordingly, a collaborative approach to enable the case company's engineering team to understand the real needs of customers, was then built on top of the grounded conceptual framework. The relevant stakeholders' (engineering, marketing/sales, clinical, usability, product management, quality and regulatory and service) involvement at the various stages of the product development process was also proposed. The two initial stages of the product development process, initial concept development stage and requirement document development stages, were found to be the key to address most of the challenges identified in the case company. However, based on the feedback collected on the initial proposal, iterating the first four stages and developing quick prototype was recommended.

By combining the appropriate techniques, especially goal-oriented observation of the customers' environment with contextual inquiry, detailed knowledge about customer needs can be obtained. Besides, the involvement of multi-stakeholders at these stages guarantees that the background of customer needs is analyzed from different perspectives so that the details of customer needs is understood clearly.

To summarize, the success of any product stems from a thorough understanding of the real needs of customers. When it comes to medical product development, understanding the real needs of the customers becomes even more than a necessity. To that end, the results of this study will help the case company, firstly, to understand the root causes for a varied set of customer needs. Secondly, it can help to focus the company's resources to what is relevant for customers. Thirdly, involving customers to understand their needs also helps to create good and long lasting relationship with customers. Finally, transcending this practice throughout the company creates organizational culture which will ultimately create motivation and a sense of ownership in the employee's minds.

7.2   Managerial Implications

In order to address the challenges identified in the case company and implement the recommended proposal, some practical steps need to be taken.

As it was proposed, by forming the right combination of roles and techniques at different stages of the product development process, the challenges identified can potentially be addressed. However, the following practical considerations need to be taken into account.

Firstly, since this proposal involves customer involvement to a greater extent (observations at customer environment for instance), a very close collaboration between the case company and customers is needed. However, due to the nature of customers' environment (hospitals), related challenges such as privacy and ethical side of it as well need to be considered further.

Secondly, the amount of resources (time, finance, human, etc.) need to be properly analyzed. For instance, when implementing the proposal in the first two key stage of the product development process by using the proposed techniques, the number of customer sites to be observed, the frequency of observation (the number of iterations), etc. need to be taken into account.

Finally, involving customers to identify and understand their needs as well as their environment shouldn't be limited to the responsibility of few roles but rather it should be an organizational culture. Doing so brings forth a sense of motivation among employees as it creates a sense of recognitions and ownership to every individual.

7.3   Thesis Evaluation

This thesis strove to address practical challenges identified in the case company with respect to understanding the real needs of customers. The following subsection evaluates this thesis from four criteria: logic, relevance, validity and reliability.

7.3.1 Logic

Firstly, looking at the logical flow of the thesis, this study was presented in the following manner. The business challenge in the case company was defined and existing practices to further identify strength and weakness areas in the case company was analyzed and presented. The result of the findings indicated that there were challenges related to understanding the real needs of customers. To address the challenges, customer involvement in different stages of product development process was found to be the key determinant. Besides, the techniques used to identify and understand customer needs were studied. On top of that, the relevant stakeholders to be involved in the process were identified. A mapping of the techniques and stakeholders to the appropriate key stages of the product development process was co-created with stakeholders and presented as an initial proposal. Finally, to validate the initial proposal, it was presented to key stakeholders and feedback was incorporated to result in a final proposal.

7.3.2 Relevance

Secondly, concerning the relevance of this study to the case company, due to the nature of the products, a robust understanding of the real needs of customers is the area the case company strives to address. In that respect, the outcome of this study addresses the practical challenges in this area. First, it will help the case company to address the root causes for a varied set of customer needs. Secondly, it can help to focus the company's resources to what is relevant for customers. Thirdly, involving customers in an effort to understand their needs also helps to create good and lasting relationship with customers. Finally, transcending this practice throughout the company creates organizational culture which will ultimately create motivation and a sense of ownership in the employee's minds. However, considering the complexity, variation and number of customer needs that the case company deals with, more study on the analysis and formulation of these varied set of needs could have contributed better to the case company.

7.3.3 Validity

Thirdly, the validation of the proposal was carried out by having a discussion with some of the case company stakeholders. Valuable feedback was collected and incorporated to shape the initial proposal. However, involving decision makers could have made a

difference to further validate and get practical feedback on how to kick start the implementation of the proposal.

7.3.4 Reliability

Finally, addressing the reliability, the data inputs for analyzing the current practices, co-creating the initial proposal as well as the feedback was firsthand information gathered from the case company stakeholders directly. Besides, as many relevant stakeholders as possible were involved in the course of this study. However, the study is limited as it didn't address the following points. Firstly, due to a number of reasons, customers were not involved as part of stakeholders to co-create the proposal, so the result reflects the case company perspective only. Secondly, considering the organizational size of the case company and complexity of the case, much more detailed analysis could have been carried out.

7.4 Final Words

This study identified practical challenges in the case company and proposed potential solution. However, the solution proposed is not a silver bullet but rather a starting point to shed light on the matter. One of the limitation of this study is that it mainly gave emphasis on benefits that can be gained from the case company perspective only. It did not thoroughly analyze the customer perspective. Besides, considering the complexity of the medical industry as well as the varied set of customers and conflicting needs that the case company deals with, a much more analysis is recommended for future studies.

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