Value Proposition Design for Medical Device Related Pressure Ulcer Prevention Solutions

Master of Science Thesis
in the Management and Economics of Innovation Programme

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Cover:
[Cover photo is retrieved from Shotbyshot.org (2012), telling the story of a baby called Marco wearing nasal prongs for nasal Continuous Positive Airway Pressure treatment.]

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Abstract

As one of the most concerning healthcare issues, Pressure Ulcers (PUs) has brought enormous pain and costs for patients and healthcare sectors, among which the Medical Device Related Pressure Ulcers (MDRPU) are especially common among young pediatric patients primarily due to their immature skin type. Thus, this research targets on the phase of value proposition design for Medical Device Related Pressure Ulcer Prevention (MDRUPP) solutions, for infants less than 1 year old receiving the nasal Continuous Positive Airway Pressure (nCPAP) treatment. In order to reach the proposed research aim, this work is conducted from different perspectives and presented accordingly through eight chapters: in the Introduction, background regarding MDRUPP is introduced, followed by the elaboration of the research aim and scope; thereafter, several theories and models such as Lean Customer Development, Value Proposition Design, Outcome Driven Innovation are introduced and integrated for the research need in Theoretical Framework; followed by the Methodology, where the entire research process including market data estimation, qualitative interviews, quantitative surveys and questionnaires are introduced; in Market Review, the number of the global customer base as well as nCPAP market potential are presented, followed by a product investigation on nCPAP devices and dressings currently in the markets; in Empirical Findings, the data collected from customer interviews with nurses, a patient’s parent and hospital purchasers, surveys as well as other scientific resources are presented; in Analysis, the values are further categorized and prioritized, in order to define value proposition with specific focus, followed by the risk analysis; Moreover, perspectives regarding the theories, methodology, as well as the outcomes of the research are discussed further; finally, a conclusion is drawn and the value of this research is summarized. This research provides a comprehensive value proposition for MDRUPP solutions, through a deep understanding of the proposed issue and supporting theories, valuable data achieved from both qualitative and quantitative research methods, followed by in-depth analysis and discussion, through which the value of this research is demonstrated to customers, the company collaborated with, and the healthcare industry in general.

Keywords: Medical Device, Pressure Ulcer Prevention, nCPAP, infants, Value Proposition Design, Lean Customer Development, Outcome Driven Innovation, preventive dressings.
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<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous Positive Airway Pressure</td>
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<tr>
<td>EPUAP</td>
<td>European Pressure Ulcer Advisory Panel</td>
</tr>
<tr>
<td>LCD</td>
<td>Lean Customer Development</td>
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<tr>
<td>MDRPU(s)</td>
<td>Medical Device Related Pressure Ulcer(s)</td>
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<td>MDRPUP</td>
<td>Medical Device Related Pressure Ulcer Prevention</td>
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<tr>
<td>nCPAP</td>
<td>nasal Continuous Positive Airway Pressure</td>
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<td>NICU</td>
<td>Neonatal Intensive Care Unit</td>
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<td>NPUAP</td>
<td>National Pressure Ulcer Advisory Panel</td>
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<tr>
<td>NSRAS</td>
<td>Neonatal Skin Risk Assessment Scale</td>
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<td>ODI</td>
<td>Outcome Driven Innovation</td>
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<td>PAP</td>
<td>Positive Airway Pressure</td>
</tr>
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<td>PUP</td>
<td>Pressure Ulcer Prevention</td>
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<td>Pressure Ulcer(s)</td>
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<tr>
<td>TEWL</td>
<td>Trans-Epidermal Water Loss</td>
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<td>VPD</td>
<td>Value Proposition Design</td>
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1 Introduction

As one of the most prevalent and severe healthcare issues, pressure ulcers (PUs) has brought massive patients’ pain and hospital spending. Moreover, PUs associated with the use of medical devices has added in more risks of wound, distortion, infection, and even death to patients receiving medical treatment. This kind of PUs is called medical device related pressure ulcers (MDRPUs), which is especially common among pediatric patients. This section provides a brief overview of PUs as background introduction, MDRPUs as the problem the research targets on, and presents the aim and scope of this work.

1.1 Pressure Ulcers

According to National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (2014b), “A Pressure Ulcer (PU) is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” (p. 12), in addition to which, other factors such as microclimate, friction, malnutrition are also among the key causes of pressure ulcers (Baharestani & Ratliff, 2007). Moreover, pressure ulcers are further categorized into four stages, with increasing severity from stage 1 to stage 4 as shown in Figure 1 retrieved from NUPAP (2014b).

Pressure ulcers (PUs) has brought enormous pain, and risks of life-threatening infections as well as economic burden for patients and healthcare sectors, thus PUs, especially in term of prevention, has drawn an increasing attention by healthcare professionals and organizations globally. PUs affects 2.5 million patients each year in the US, with an average cost of $43,000 to treat each PU, which results in $9.1 billion to $11.6 billion of total cost, and 60,000 deaths every year in the US (Berlowitz et al., 2011). Furthermore, since 2012, reimbursement for PUs developed during hospitalization are no longer provided by Centers for Medicare & Medicaid (CMS) in the US, which means it becomes the hospitals that have to cover all the costs associated hospital acquired PUs (Berlowitz et al., 2011). Comparing to PUs treatment, prevention has several key benefits. Prevention cost is 60% lower than treatment (Hughes, 2008). Moreover, prevention also reduces patients’ pain and hospital costs, not only in terms of capital, but also nursing resources, hospital beds, facility uses, etc. Thus, PU prevention possesses various obvious advantages, thus is more embraced by patients and healthcare sectors comparing to treatment.

1.2 Medical Device Related Pressure Ulcers

Within PUs mentioned, a large proportion is due to the use of medical devices. According to National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (2014a), “Medical device related pressure ulcers (MDRPUs) are pressure ulcers that result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure ulcers generally closely conforms to the pattern or shape of the device.” (p. 117); the
devices with high risks vary according to medical treatments received, but the common devices associated are respiratory masks, nasal cannulas, tracheostomy faceplates and securement devices, cervical collars, etc. Moreover, children and infants have higher risks to develop MDRPUs comparing to adults. According to Baharestani & Ratliff (2007), for infants and children, over 50% of PUs are associated with equipments and devices. In comparison, up to 34% of PUs are medical device related for adults, which means most of the PUs for adults are conventional, due to various daily activities (Visscher & Taylor, 2014). Common sites are bony prominences such as sacrum, heel, occiput, nose, ears (Schober-Flores, 2012).

In order to integrate the risk factors causing MDRPUs, a Fishbone Diagram is created as shown in Figure 2.

Fishbone Diagram (also known as Cause & Effect Analysis, Ishikawa Diagram), developed by created by Ishikawa (1968) is a tool to demonstrate the risk factors that can cause a certain outcome. Based on literature study, the causes of MDRPUs are categorized into four main groups: Receiving Population, Medical Devices, Skin Conditions, and Human Factors. In terms of receiving population, malnutrition, length of hospital stay, other critical diseases, and the young and old age groups, etc., have a big impact the development of MDRPUs (Baharestani & Ratliff, 2007). Especially, for premature neonates of less than 37 weeks of gestation, absorption of topical products is higher, infection and water loss risks are higher, and their skins are more likely to be affected by mechanical forces, all of which add in high risks (Baharestani & Ratliff, 2007). In terms of Medical Devices used, a design flaw, rigid and stiff materials, and limited choices of size and shape range will add in the risks causing MDRPUs (Fletcher, 2012). Regarding Skin Conditions, pressure, shear, friction, microclimate (e.g., moisture, temperature) are the dominant risk factors.

Figure 2. Fishbone Diagram for MDRPUs
(Baharestani & Ratliff, 2007), which are also the key focuses of this work. Especially for premature neonates with less than 37 weeks of gestation, their skin structure is immature, therefore, absorption of topical products is higher, infection and water loss risks are higher, and more likely to be affected by pressure, shear, and friction (Baharestani & Ratliff, 2007). Regarding Human Factors, the knowledge, resources and caring procedures of caregivers are essential according to the guideline of NPUAP (2014a). Risks assessment tools such as Braden Q, Neonatal Skin Risk Assessment Scale (NSRAS), and regular skin inspection are also required, together with established guidelines and practices during hospitalization (Schober-Flores, 2012). In this work, the risk factors causing MDRPUs are further focused into Skin Conditions, Age & Skin Vulnerability, and the Sizes and Shapes of Medical Devices, which can be controlled with the purpose of value creation of a healthcare solution.

1.3 Aim & Scope

Based on the background introduction above, it can be observed that Medical Device Related Pressure Ulcers Prevention (MDRPUP) especially for small children requires a more innovative solution from healthcare companies, due to their vulnerable skin structure and the damages MDRPUs can cause.

Thus, in order to solve this genuine problem, this work aims at creating a new value proposition design for MDRPUP solutions, which is collaborated with the company named “Medical Device Incorporated” in Northern Europe. With a thorough literature research followed by empirical data analysis, the scope of this work has been narrowed down into

- neonates/infants from new-born to 1 year old;
- with nCPAP (Nasal Continuous Positive Airway Pressure) masks & cannulas related PUs;
- with MDRPUs occurring on the head.

Reasons for each dimension are explained in the following subsections.

1.3.1 Target Population

Reasons why to target on neonates/infants from new-born to 1 year old is explained as follows. According to Schlüer, Halfens, & Schols (2012), infants from new-born to 1 year old have the highest MDRPU incidence which is 49.3%, comparing to other age groups. The main reason of such high incidence is due to their immature skin barriers (Schober-Flores, 2012), which are not able to protect from the harm of mechanical forces and complicated microclimate. And the inability to sense devices properly nor to communicate the discomfort also added in more risks (Fletcher, 2012). Furthermore, a broad search of existing products indicates that the markets for infants and small children are much underserved in terms of both volume and product feature, comparing to adult markets. Moreover, from an economic point of view, the infant/neonate market represents good potential of economic return through higher chances of premium pricing. From an emotional perspective, people would like to help those lovely babies out of sympathy when their lives have just begun. Furthermore, once the competence gained from infant markets is established by serving the most vulnerable skin, this knowledge and expertise can be transferred into older pediatrics and adult markets with solutions that are gentle enough, however, this process can never be reversed.

In addition, comparing literature studies of infants less than 1 year old (Fischer et al., 2010; Yong, Chen, & Boo, 2005; Buettiker et al., 2004) with pediatrics from 1 to 18 years old (Schlüer et al., 2014; Schlüer et al., 2012), it can be found that the rages of age, devices used, settings, and ulceration sites are much broader when it comes to older pediatrics, and the incidence varies with different conditions applied. Therefore it is not possible to draw a common conclusion for pediatrics up 18 years old. However, infants less than 1 year old is more convergent to the setting of neonatal department especially within the setting of the Neonatal Intensive Care Unit (NICU), where respiratory treatment is received.
1.3.2 Target Devices
As the performance of respiratory devices has been increasing, the traditional method of constructing invasive artificial airways has been obsolete due to the enormous patients’ pain it can bring. Continuous Positive Airway Pressure (CPAP) is a form of ventilator that provides continuous airway pressure to keep the patients’ airway open when they are not able to breathe on their own bases. It’s a non-invasive method with no needs for artificial airways, thus it’s widely used among especially babies. Moreover, the CPAP device is usually attached with nasal interfaces, such as nasal masks as shown in Figure 3 left (understandingprematurity.com, 2010), and nasal cannulas with prongs as shown in Figure 3 right (Cheung, 2011), which is referred as Nasal Continuous Positive Airway Pressure (nCPAP).

CPAP with its proven efficiency and advantage of less patients’ pain has been widely used as a means of ventilation support. According to Chow (2013), within NICU in Australia and New Zealand, 93.3% of neonatal patients need ventilation support, among which 79.8% are nCPAP. Thus, it can be calculated that the total percentage of CPAP use inside NICU is approximately 74% by multiplying those two figures mentioned, which provides evidence of its prevalence. Nasal interfaces especially nasal masks and nasal cannulas are the most widely applied attachments to CPAP machines. Therefore, nasal CPAP short as nCPAP is the type of device used most frequently in NICU which is 74%.

Apart from its prevalence, nCPAP also generates a very high risk for MDRPUs. According to Fischer et al. (2010), the nCPAP related PUs incidence is 42.5% inside NICU, and the risk increases as gestational age decreases. Moreover, as two of the most common attachments, 29% of neonatal patients using nasal masks have developed MDRPUs, and this figure is slightly higher for nasal cannulas which is 35% (Yong, Chen, & Boo, 2005). Therefore, it can be concluded nCPAP is the most common device used for neonatal patients, and its risk for developing MDRPUs is also very high. The most common interfaces between the CPAP machines and anatomical sites are nasal masks, and nasal cannulas with prongs, which are the target devices of this work.

1.3.3 Target Anatomical Sites
Kottner, Wilborn, & Dassen (2010) have further proved that the chances of developing MDRPUs are much higher among pediatrics than adults. Furthermore, the anatomical sites of MDRPUs for children are mostly located at nose, occiput, chin, neck, ears, etc., and with their ages increasing, a higher chance for MDRPU sites moving down to sacrum and heels (Kottner, Wilborn, & Dassen, 2010). In other words, for neonatal patients, the most likely anatomical sites of MDRPUs are located at the head area, including nose, cheeks, ears, neck, occiput, etc., and these areas are further narrowed down specifically for nCPAP device as shown in later chapter.
1.4 Outline
To conclude, this paper aims to create a new value proposition for MDRPUP solutions, for infants less than 1 year old, wearing nCPAP masks or cannulas on the head. In order to reach such research aim, this paper consists of the following sections; in Theoretical Framework, several up-to-date models are introduced serving as the theoretical backbones and guidance; Methodology describes the process of how qualitative and quantitative data are captured, analysed and prioritized; Market Review provides an overall picture of MDRPUP market conditions to assess the business potential; in Empirical Findings, data regarding customer interviews, surveys, stakeholder questionnaires are presented; followed by the section of Analysis, the customer insights gained are further assessed and optimized, based on which value proposition is defined and risk is assessed; in Discussion, the previously used models, data, and analysis are raised into a higher level to further discuss its indications and trends behind; in the last section of Conclusion, a strategic recommendation as well as a summary of the research outcome are provided.
2 Theoretical Framework

In this chapter, several theories and models used in this research are introduced, among which the concept of Lean Customer Development, Value Proposition Design, Outcome Driven Innovation, Risk Matrix consist the primary part of this theoretical framework.

2.1 Lean Customer Development

Customer Development by Blank (2006) is a hypothesis driven approach to understand customer insights and behaviours, and interpret them further to develop products/services that serve the genuine customer needs. Based on this concept, Lean Customer Development (LCD) is developed by Alvarez (2014), with a more agile and pragmatic approach not only for start-ups, but also for established companies exploring new business opportunities. LCD driven by 5 steps: form a hypothesis; find potential customers to talk to; ask the right questions; make sense of the answers; figure out what to build to keep learning (Alvarez, 2014). These steps form an iterative and continuous process in order to dig deeper into customer insights. In comparison with the Lean Start-up Feedback loop- “build, measure and learn” by Ries (2011), Alvarez (2014) suggests to start with thinking and learning to avoid unnecessary expenses by first building models and prototypes that later turns out no customers want. Therefore, the build-measure-learn loop can also be reversed as reflected by LCD, starting from learning market conditions and customer insights, to measure their wants and needs, to come up with the right prototypes or models and keep learning, until the final product that customer would like to purchase forms up.

The concept of LCD and its 5 steps are embedded into and reflected by the entire process of this work, serving as the theoretical cornerstone. The process of starting with learning market conditions, to customer insights before building the product concept is also reflected in this work.

2.2 Value Proposition Design

The Business Model Canvas developed by Osterwalder & Pigneur (2010) is a well-embraced tool to create, deliver and capture value for companies. As an plug-in integrated to the Business Model Canvas, the concept of Value Proposition Design (VPD) is developed by Osterwalder et al. (2014), with a particular focus on value creation. This concept provides an effective approach regarding value creation through the Value Proposition Canvas that specifically targets on customers’ pains and gains as well as their jobs.

The Value Proposition Canvas as shown in Figure 4 retrieved from Osterwalder (2012), has two sides according to Osterwalder et al. (2014): Customer Profile on the right side clarifies an in-depth understanding of a specific customer segment and their insights; the Value Map on the left side describes the features of the value proposition corresponding to the customer segments; and the fit between two sides must be achieved to ensure the value proposed serve customers’ genuine needs. The Customer Profile is further broken down into three parts: Customer Jobs describes what the customers are trying to accomplish in their work or lives; Pains illustrates the obstacles holding them back to get their jobs done successfully; Gains describes the benefits they are seeking in order to deliver a good outcome (Osterwalder et al., 2014). Meanwhile, the Value Map can also be divided into three parts: Pain Relievers illustrates how the products/services eliminate or minimize the customer pains; Gain Creators describe how the products/services create or maximize customer gains; and based on all above, the Product & Services illustrates the value proposition designed for such customer segments with prioritized features (Osterwalder et al., 2014).
In terms of Customer Jobs, it can be observed from various perspectives, including not only what they do and say, but also what they see and hear, what they think and how they feel about their jobs, which consist the Empathy Map by Osterwalder & Pigneur (2010) as shown in Figure 5 retrieved from Bland (2012). As suggested by Osterwalder et al. (2014), Customer Jobs is not solely about their functional jobs, but also their emotional and social jobs. More precisely, apart from the job procedures, their feelings, other people’s perceptions and behaviours would also have a big influence on their own behaviours, just as reflected by the Empathy Map. Therefore, the two frameworks mentioned can be well integrated, altogether support the process of the concept of LCD.
2.3 Outcome Driven Innovation

As innovation becomes more customer-centric, rather than solution-driven, customer needs have become an indispensable starting point of each innovation. However, according to Ulwick (2005), there is no universal definition of what customer needs include, or what form it contains. Therefore, it causes confusions when conducting customer interviews that companies do not know exactly what inputs to capture, customers do not know what inputs are needed. As a result, the customer interviews are very likely to end up with the “requirements” of the final solutions directly from customers such as product features and specifications, which is referred as “voice of the customer” by Ulwick (2005). An example can be the well-spread quote from Henry Ford, the founder of Ford Motor Company, saying that “If I had asked my customers what they wanted, they would have said a faster horse”. Although it is essential to hear from customers about their insights nowadays, it is dangerous to follow such solution-oriented requirements into further production, without noticing the fact that quite often customers are not entirely sure what the final solution would be like, or how it can be achieved technically; in contrast, they always know about what jobs they do, what outcomes are desired out of their jobs, and what constraints are holding them back. Therefore, it can be observed that customer insights are essential, but it is the method to capture the right ones that matters.

Thus, in order to provide a method to gain customer insights through their jobs, outcomes and constraints, Outcome Driven Innovation (ODI) by Ulwick (2005) emphasizes “jobs to be done”, rather than the “voice of the customer”. More precisely, jobs are regarded as the basic analysis unit, together with customers’ desired outcomes and constraints, the customer needs can be defined. In such way, innovation is driven by the outcomes that maximize the desired and minimize the constraints, rather than the requirements of final solutions heard from customers. It can be seen that the thinking of ODI is much aligned with VPD from Osterwalder et al. (2014) including Customer Jobs, Pains and Gains mentioned above, both of which focus on the what customers do, what benefits and problems are through their jobs, rather than to let customers jump into the final solution directly.

Moreover, after gaining such customer insights, it is beneficiary to further investigate the opportunity each stands for, so that the resources can be utilized the most efficiently. Ulwick (2005) refers an opportunity as an underserved outcome (including jobs, desired outcomes, and constraints) that customers want to achieve but cannot do it in a satisfying way with existing solutions. Therefore Ulwick (2005) has developed the Opportunity Algorithm, which is described as Opportunity = Importance + (Importance – Satisfaction, 0)\text{max}. In other words, the outcomes or product features with highest importance, but are not/less satisfied yet in current markets represent the highest opportunity. In such way, the resources can be spent to these underserved outcomes through prioritization, with the highest opportunities and economic returns. It can be seen that the process of outcome prioritization also reflects the thinking of continuous learning in LCD.

Based on the Opportunity Algorithm, Ulwick (2005) has developed the tool of Opportunity Landscape to visualize the data for analysis, as shown in Figure 6. According to Ulwick (2005), when the degree of Importance and Satisfaction of outcomes are deemed as the two axes, and each is quantified with the value ranging from 1 to 5, as low to high, the outcomes can be marked at the Opportunity Landscape representing an opportunity score using the algorithm above. Moreover, as it can be seen that the map is divided into three categories: the “Overserved” means the outcomes are well satisfied, thus should be realized in a cheap way with performances that are not necessarily perfect, but are just fine; the “ Appropriately Served” means these outcomes represent high existing competition, they are good to have but not a must, and their adjacent functions are beneficiary to explore more to make something new out of the existing competition; the “Underserved” in the lower right corner represents outcomes that companies should emphasize on with very promising opportunities, and these are the core and differentiating features the products will possess (Ulwick, 2005). As designed by Ulwick (2005), when the opportunity score is high ranging from 5 to 9, it will fall into the category of underserved outcomes; for opportunity score starting from 1 but less than 5, this outcome will fall into the category of either overserved or appropriately served outcome depending on
the value of each parameter. In such way, not only the outcomes can be prioritized, it becomes also clear that what strategy to apply for each outcome.

2.4 The Risk Matrix

As an increasing number of companies emphasize on the power of innovation to create competitive advantages, there might be many new projects developing simultaneously. Thus, in order to make wise decisions and distribute proper resources of each project inside a company, a clear picture of risks in advance of each project is critical (Day, 2007). As Nagji & Tuff (2012) have grouped innovation into types of Core, Adjacent and Transformational Innovation depending on the degree of familiarity in terms of both market conditions and future products/services. Similarly, according to Day (2007), the Risk Matrix serves as a tool illustrating the risk of a company’s innovation portfolio, through a scoring system from both market and product perspectives. As shown in Figure 7 (copyright by Adj. Prof. Bengt Järrehult), the probability of success or failure of each innovation can be decided through two dimensions: the x axis represents how familiar the future product or service is to the company; the y axis represents how familiar the intended market conditions and customer behaviours about this innovation is to the company (Day, 2007). When both are similar with current conditions within the company, the probability of success is high, and will fall into the lower left corner, representing a lower risk; when both dimensions are new to the company, the probability of success is lower, and will fall into the upper right corner, indicating a higher risk (Day, 2007).

The value of both axes is determined through a quantitative survey containing questions from both product and marketing perspectives, as shown in Table 1 retrieved from Day (2007), and the value of probability of success can be positioned in the Risk Matrix according to the sum of scores in each dimension (Day, 2007). In such way, the risk of each innovation can be evaluated to assist the decision making in selecting projects to proceed.
Figure 7. The Model of Risk Matrix

Table 1. Quantitative Survey Questions of Risk Matrix

<table>
<thead>
<tr>
<th>Intended Market</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<tr>
<td>Customers’ behavior and decision-making processes will...</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Our distribution and sales activities will...</td>
<td>1</td>
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</tr>
<tr>
<td>The competitive set (incumbents or potential entrants) will...</td>
<td>1</td>
<td>2</td>
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<td>4</td>
<td>5</td>
</tr>
<tr>
<td>... highly relevant</td>
<td>... somewhat relevant</td>
<td>... not at all relevant</td>
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<td>Our brand promise is...</td>
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<td>2</td>
<td>3</td>
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<td>5</td>
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<tr>
<td>Our current customer relationships are...</td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Our knowledge of competitors’ behavior and intentions is...</td>
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<th>Product/Technology</th>
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<td>Our current development capability...</td>
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<td>Our technology competency...</td>
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<td>Our intellectual property protection...</td>
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<td>Our manufacturing and service delivery system...</td>
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<td>5</td>
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<tr>
<td>... are identical to those of our current offerings</td>
<td>... overlap somewhat with those of our current offerings</td>
<td>... completely differ from those of our current offerings</td>
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<td>The required knowledge and science bases...</td>
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<td>5</td>
</tr>
<tr>
<td>The expected quality standards...</td>
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</tr>
</tbody>
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TOTAL
3 Methodology
This chapter demonstrates the method on what and how data is collected and analysed, in accordance with the theoretical framework proposed. This case study is conducted within the setting of a medical device company in Northern Europe, which has added in much professional expertise and resources to achieve the proposed research goal.

First, an overall research structure is presented as follows. Guided by the 5 steps of LCD shown previously, the customer insights have been captured, though the process as follows.

- First, the hypothesis of the necessity of superior MDRPUP solutions for infants less than 1 year old receiving nCPAP devices has been formulated, based on literature study and market review.
- 8 direct interviews have been conducted through company contacts. In addition, inputs from a scientific perspective have been gained through both literature study and conversations with R&D and Marketing managers within the company.
- Then interview guides regarding each customer segment mentioned are created, around the topics of Customer Jobs, Pains and Gains by VPD.
- Then interview outcomes are summarized and put into the model of the Empathy Map described previously, further analysed through the framework of Value Proposition Canvas by VPD. The hypothesis can be validated at the stage as well.
- The outcomes consisting of Pain Relievers and Gain Creators can be integrated. Furthermore, surveys guided by the concept of ODI have been handed over to a neonatal department in Sweden, with 8 responses as a second round input to prioritize those outcomes. It also reflects the thinking of continuous learning and iterative processes of LCD. The final value proposition can be defined from these prioritized outcomes, and the probability of success can be determined by the company’s internal stakeholders through Risk Matrix thereafter.

Moreover, each research method used in this work is introduced with more details as follows.

3.1 Literature & Market Study
As the initial learning regarding MDRPUP issues, scientific study have been conducted through literature review in order to provide sufficient scientific support. Knowledge on the causes of MDRPUs are summarized in Figure 2, based on medical papers. Moreover, the product requirements from a scientific view has also been gained through conversations with internal managers as well as external sources the company possesses, in order to grasp a comprehensive value proposition together with customer insights.

The market data regarding customer base as well as nCPAP market conditions are gained through online data search and analysis, which is one of the emerging but important research methods, referred as e-research by Bryman & Bell (2011). As the NICU settings are the places where nCPAP are most frequently used among neonatal patients, the annual NICU admissions in 14 countries (incl. the USA, UK, China, South Africa, Germany, etc.) are investigated online each by each. Direct data are optimal, however when direct data is not available, calculations based on annual births and NICU admission ratios have been conducted, to estimate the annual NICU admission within the country. Countries with similar medical and population conditions are with the most relevance when conducting such calculations, in order to make the most accurate estimation. Thereafter, the total annual number of patients receiving nCPAP treatment can be estimated within the 14 countries. The online data search together with quantitative estimations provide significant market data for the company as a starting point to pursue a new business opportunity.
3.2 Customer Interviews
As the most common qualitative research method, the interview provides flexibility to verify hypothesis and capture broad inputs within a relatively short period of time (Bryman & Bell, 2011). Thus, interviews are conducted among 8 customers in total, within customer segments of Nurses/Healthcare professionals, Patient’s Parents, and Hospital Purchasers. Face-to-face interviews have been conducted in Sweden with 2 pediatric nurses, 1 neonatal nurses, 1 pediatric patient’s father, 2 purchasers for hospitals (1 for nCPAP, 1 for dressings); and phone interviews have been conducted with 1 respiratory nurse and 1 skin care professional to China. These three customer segments are selected in order to gain customer insights from various perspectives.

In order to make the interview outcome valid for the proposed aim, interview guides have been designed around the topic of Customer Jobs, Pains and Gains based on the theory of VPD introduced, regarding the customer segments of Nurses/Healthcare professionals as shown in Appendix A and Appendix B respectively, Patient’s Parents, as they are the ones directly dealing with MDRPUP issues. Therefore, these 6 interviews can be referred as semi-structured interviews with both prepared topics and flexibility to adapt in each situation (Bryman & Bell, 2011). Regarding the customer segment of hospital purchasers, although they do not directly interact with MDRPUP, they have expertise regarding the product features, and more objective and holistic views on MDRPUP. According to Bryman & Bell (2011), unstructured interview type allows interviewees respond more freely and gain a broad information set. Thus, the interviews have been conducted with 2 hospital purchasers by probing the 3 topics with an unstructured method, for the purpose to gain holistic picture, overall understanding of current product performance, and purchasing standards and procedures. Combined with both semi-structured and unstructured interviews with the proposed 3 topics, customer insights have been captured with various perspectives in a valid and organized way.

Since the value proposition is aimed in a global scale, the author as a native Chinese speaker has made phone interviews to China as mentioned. The respective interview guides are translated into Chinese beforehand by the author. In general, the phone interviews took only 15 to 25 minutes each comparing to the face-to-face interviews which normally took 45 to 60 minutes. The reason could be due to the less physical interaction and communication, and they could not be able to show their products or caring methods through the phone. Therefore, the face-to-face interview is optimal to capture the most data when situation allows.

Notably, it would be great to integrate another qualitative research method, ethnography which means the immersion into the research setting to observe the behaviour for a considerable period of time Bryman & Bell (2011), into this research. However, due to time limits, and the ethical issues related to patients’ privacy and hospital operations, the ethnography has not been possible. Nevertheless, the nurses have shown much about their procedure when undertaking MDRPUP activities during the interview, such as dressing application, device position, product selection, etc., which has given practical examples regarding how these activities have been undertaken during their daily work.

3.3 Customer Surveys & Stakeholder Questionnaire
Although the qualitative method has advantages of a broad and quick of information gathering, the shortage of this method still exists, such as subjectivity pointed out by Bryman & Bell (2011). Thus, after first round of qualitative data gathering, quantitative methods have been chosen, to optimize the values and indicate risk numerically.

After gathering all the interview outcomes, these outcomes have been fitted into the inputs of customer surveys guided by ODI. Each outcome has been assessed by the measurement of Importance and Satisfaction with scale 1 to 5 as low to high for each, as described previously. The survey has been sent to a
hospital neonatal department, and eight responses from neonatal nurses have been received after two days. Thereafter, the score of Opportunity can be calculated based on the survey outcome and the Opportunity Algorithm as introduced above. Based on the Opportunity score, these outcomes can be prioritized, the result of which is shown in later chapter.

After the value proposition was defined, an internal workshop has been conducted within the company, to complete the stakeholder questionnaire as shown in *Table 1*. Since the two dimensions of the questionnaire (Market & Customers, and Products & Services) requires internal expertise from both R&D and marketing division, 3 R&D managers and 1 marketing manager have been engaged as a joint effort. The dimensions of Marketing & Customers, and Products & Services consist of 6 and 7 measurements respectively, with value from 1 to 5 for each. After summing up the scores for each dimension, the probability of success can be accurately positioned on the Risk Matrix which is shown in later chapter.

Thus, it can be observed that these quantitative method has added a more accurate and straightforward presence of the data previously captured from qualitative methods. Thus, by combing both qualitative and quantitative methods, the overall research method can be referred as the mixed methods by Bryman & Bell (2011). The mixed methods can complementing and facilitating with each of the two methods, by adding in objectivity and accuracy to qualitative method, and the connection with people and society to quantitative method as well (Bryman & Bell, 2011). The advantage can also be reflected in this research: both qualitative and quantitative methods have been applied as initial learning, thereafter, the qualitative customer interviews was applied to gather data in a broad range, followed by the quantitative method to optimize and evaluate these data, which has well served this research purpose.
4 Market Review

In this chapter, data about customer base, nCPAP market potential in Europe, and existing products are illustrated and analysed further, in order to assess the business potential and lead the right directions. Regarding Customer base, the number of neonatal patients in NICU is estimated across 14 countries based on direct online data search and calculations. This is followed by the data of total units of nCPAP devices and attachments sold/will be sold annually within Europe, from the year 2011 to 2019. Moreover, in order to gain a comprehensive view of products currently existing and to further analyse the trend of MDRPUP, a broad competitor product search is conducted among over 15 global brands. These products are categorized into medical devices and dressings, with analysis of pros and cons to generalize the trend.

4.1 Customer Base

As the setting of NICU is where the most of nCPAP devices are used, the annual NICU admission is investigated across 14 key markets globally including the USA, UK, China, Japan, Germany, France, etc., in order to assess the size of customer base. Both direct data search and calculations are made to estimate the total size of target users for each country.

According to a publication from Canadian Premature Babies Foundation (2014), preterm babies occupies 62% of total NICU admission, among which 14% are with gestational age of 27 weeks or less, 26% are with 28 to 31 weeks, and 60% are with 32 to 36 weeks of gestational age. With these figures, in the case that direct data is not available for a certain country, if the total number of preterm babies born per year is available, total annual NICU admission can be estimated. According to statistics from Health Newborn Network (2012), the number of preterm babies born annually, as well as live births globally are available. Therefore, for countries where direct data is not available, estimations across key markets in 14 countries are estimated with a total sum of 1,684,000 annual admissions in NICU.

As mentioned above, the total using rates of nCPAP in NICU is 74%, thus the total number of patients using nCPAP in NICU per year within these 14 countries is \(1,684,000 \times 74\% = 1,246,000\), within these 14 countries. Apart from that, there are also neonatal patients that need nCPAP treatment but not so sick to go to NICU, therefore the total size of users is over 1.3 million across the 14 countries. Furthermore, the average treatment days in NICU is 15 days per year per patient (Fischer et al., 2010), therefore the total nCPAP treatment days per year are 18,690,000 days within 14 key markets.

4.2 nCPAP Market in Europe

Apart from the size of the customer base, the use of nCPAP as well as the nasal interfaces including nasal masks and cannulas also influence the potential opportunity of MDRPUP solutions, therefore the market sizes of nCPAP and its nasal interfaces have been investigated.

According to a well reputed but confidential source owned by the company, the units sold per year of nCPAP machines, nasal masks, nasal interfaces (including nasal prongs) in Europe are all expected to grow by 5% to 12% comparing the year 2015 with 2019. The nCPAP machines sold in Europe in 2019 are predicted as 6 digits. The reasons why units sold per year will grow is due to: the proven effectiveness and painless of nCPAP treatment; many products currently available on markets which makes it the switching costs very high; its price is 2 to 3 times lower comparing to other Positive Airway Pressure (PAP) machines, which offers nCPAP a competitive advantage; and the increasing demand of both hospital and home care. Meanwhile, as attachments or accessories of nCPAP machines, the number of nasal interfaces sold will increase accordingly, and quite many are for single use. The nasal masks and nasal interfaces sold in Europe in 2019 are predicted with a total number of seven and six digits respectively. Therefore, it can be observed
that the nCPAP market is featured with large volumes and it will still be increasing in the coming years, which offers the preventive products of MDRPU a promising opportunity.

4.3 Product Review

In order to gain a comprehensive view of products currently existing and to further analyse the trend of MDRPUP, a broad product information search is conducted with over 15 global brands. Products are categorized into nCPAP devices (nasal masks, and nasal cannulas), and dressings as shown below.

4.3.1 nCPAP Devices

Regarding nCPAP devices, the performance has been increasing in terms of good sealing and fitting, device-skin interface design, lightweight materials, etc., such as the design of built-in flaps of Profile Lite Youth Nasal Mask by Philips, and bendable wire in order to create fit and better user experience from MiniMe® by Carefusion. Moreover, Patent families have been created to secure IP positions for those key players, such as Carefusion, Philip Respironics, etc. since 2000s. Those patents are concerned with the design of nasal masks, gas monitoring technology, etc., to integrate the whole system.

However, despite all the improvements the device manufacturers has been innovating on, drawbacks still exist. No matter how soft these masks are, they still leave indentation on patients’ faces due to high level of pressure placed, which is a common factor for developing MDRPUs. Moreover, the factors of pressure, friction/shear are the aspects device manufacturers have been focusing on, however, the skin microclimate including moisture, temperature level, which is also a very important factor causing MDRPUs, has been overlooked.

4.3.2 Dressings

There currently exist dressings for PUs in general, such as Duoderm®, DERMAPAD, Mepilex® Lite, etc., by putting them on as a contact layer between the skin and devices to reduce the MDRPU occurrence. However, none of them are specifically focused on nCPAP related PUs nor on infants with the most vulnerable skin type. Moreover, they are more from PU treatment perspective rather than prevention, which is not a superior solution since it’s more expensive and generates more patient pain. Although, those products provide a size and shape range for different anatomical sites, they need cutting from nurses which consume much time with poor results. Furthermore, those products are more for pressure redistribution purpose, little is mentioned about skin microclimate such as moisture, temperature, etc. Therefore, due to the reasons mentioned, there does not exist a superior solution for nCPAP related PUs for infants.

Thus, it can be concluded that both existing nCPAP devices and dressings are not good enough to eliminate or significantly reduce nCPAP related PU occurrence, specifically focusing on infants’ vulnerable skin.

In addition, it must be noticed that there has started a new trend towards device-dressing integrated solution by device manufacturers, such as Intersurgical Ecolite™ Oxygen Mask/nasal cannula with ear guards, Optiflow™ Junior Nasal Cannula/Wigglepad™, etc. These products, though not good enough to solve the problem perfectly, but has put a risk on dressing manufacturers. Because MDRPUs are generated from devices, and dressings are more of attachments or accessories, if the device manufacturers provide a perfect integrated solution or a device that does not cause MDRPUs, there might not be much opportunity left for stand-alone dressing manufacturers. Furthermore, such integrated solutions have the advantages as one entire package, the size, design and functions between devices and dressings can be more fitting and complementary.

Through this chapter, it can be concluded that the MDRPUP market size for infants less than 1 year old receiving nCPAP treatment is promising; the market potential nCPAP devices is positive in the coming
years; there are no superior solutions currently on markets that can eliminate MDRPU occurrence for infants less than 1 year old receiving nCPAP treatment; There has started a new trend towards a device-dressing integrated solution that is worth noticing.
5 Empirical Findings
In this chapter, empirical data regarding customer interviews, scientific findings, and customer surveys are demonstrated. These data have been gained through online resources, face-to-face and phone interviews, quantitative surveys, scientific study and inputs from professionals inside the company. During the first round of empirical data collection of customer insights, 8 customer interviews have been conducted. Then, scientific findings gained from both literature study and conversations with professionals inside the company. At last, a quantitative survey guided by the theory of opportunity analysis by ODI as stated above, has been carried out containing the previous data, for the purpose of prioritization.

5.1 Customer Interview Outcomes

5.1.1 Nurses/Healthcare Professionals
As the nurses and other healthcare professionals from the hospital are the customers applying devices and dressings to their patients with the most direct experience, insight from this customer segment is significant. The 5 interviewees from this customer segment are 2 pediatric nurses in Sweden, 1 neonatal nurse in Sweden, 1 respiratory nurse in China, and 1 skin care doctor in China.

Before the Empathy Map is presented, some basic conditions are described first according to one neonatal nurse. The neonatal incubator conditions are kept with temperature from 27 °C to 35 °C; relative humidity from 50% (for neonates with 29 weeks of gestation or more) to 95% (last for 2 weeks for neonates with less than 29 weeks of gestation). Regarding devices used, for small neonates (less than 1500g), nasal masks are used as their nostrils are too small to fit in the prongs; for bigger neonates, nasal cannulas with prongs attached can also be used; sometimes, they use them interchangeably to avoid pressure targeting on certain areas so that MDRPUs can be prevented. As shown in Figure 8 retrieved from Wilson (2012), common MDRPU sites for neonates or infants are junction between philtrum and nostrils, and up to nose bridge between the eyes when using nCPAP masks (the areas in red); around columna inside nostrils when using nCPAP prongs (the areas in blue); other common sites are cheeks, behind the ears, and forehead. Moreover, according to interviews with all the 5 nurses and healthcare professionals, the Empathy Map for this customer segment is summarized in Figure 9, with the picture source from Howtodrawfunnycartoons.com (n. d.).

![Figure 8. Common Ulceration Sites for Infants](image-url)
**Think & Feel**: they think there are not enough time and people dealing with MDRPUP, and to sustain patients’ lives are the most significant part of their jobs, so MDRPUP can be put as lower priority when it comes to urgent situations. Though no risk assessment tools such as Braden Q or NSRAS are used, regular skin check is done out of nurses’ experience generally every 1-3 hours. Moreover, fixation tapes for infants have never been good enough, because it cannot stay on under humid conditions and can peel off skin tissues when removing. They also feel stressful and powerless when they see those tiny babies wearing these devices, and they know it will harm them more or less but they don’t have another choice. Nurses have also mentioned it would be good to have perfect devices with no need for extra dressings, and they can also prevent from MDRPUs, however, devices nowadays are far from perfect.

**Say & Do**: a hydrocolloid dressing—Duoderm® is currently applied for neonates around the nose for prevention purpose before devices are put on. And these dressings are applied on older pediatrics older than 1 year only when irritation occurs. Premature babies (less than 37 weeks of gestation) are very commonly seen in neonatal department, and their skin is very vulnerable due their immature skin. Moreover, there are no fixed terms on when to change another dressing or fixation tapes, but it’s up to nurses experience and observation. To inspect skin and devices and keep everything in order, ensure no gas leakage, and the stay-on of both devices and dressings are daily jobs. It is important to choose a suitable device for each patient with different age and looks, and sometimes they are changed alternatively to avoid pressure on several single areas. Furthermore, all current dressings have to be cut into different shapes and sizes for each infant,
which consumes much time, and the results are not satisfying as their faces are too tiny to make any mistakes.

**See & Hear:** noses are the areas MDRPUs happen the most on infants, and redness (Stage 1) almost occur on every baby, but severe wounds have not been seen often, one of the reasons are the efforts on prevention. Nurses have known more about MDRPUP these years, as it has brought much patient pain and budget, and drawn much attention. Unlike Sweden where expenses are covered by hospital, in China, dressings are not included in social welfare, so the patients have to pay by themselves. However, a respiratory nurse in China indicates that patients are willing to do so as they understand that dressings are important to reduce discomfort and prevent MDRPU.

**Pains:** one of the problems dressings have is that they sometimes move to a wrong place, and it can block the air way, which is very dangerous. And sometimes the devices must be worn for a long time, but the dressings cannot stay that long especially under highly humid conditions. It’s also a big problem that the nurses have to cut the dressings into different sizes and shapes before applying, which consumes too much time on an everyday basis. These dressings cut by hand are not satisfying as mentioned above, so some hospitals in the US even use the invasive way back due to such time limits. Many dressings and fixation tapes peel off skin tissues and cause pain when removed, which is a second damage. The dressing Duoderm® currently being used absorbs moisture since it’s made of hydrocolloids, which is not good for infants since their skin barrier is incomplete and will lose the water their skin needs, so the vulnerable skin type is also a problem, especially among infants and senior people. Some dressings make skin get wet, too warm and itchy, which will decrease the tissue tolerance. An unfitting device with rigid materials in for example, the headgears put a big risk on MDRPUs. Apart from that, the feeding tube is another common source of MDRPUs, and the intranasal ulcerations caused by high air pressure is hard to notice in advance, and yet no effective way to deal with.

**Gains:** a perfect sealing and combination among devices, dressings and faces are important. The dressings must be intuitive and easily applicable with a wide size and shape range. Since infants’ are very tiny, the product design must be accurate to avoid mistakes, such as blocking the air ways. Since it is mentioned that the conditions in neonatal incubator and the NICU are very humid, it is significant that such dressings or fixation solutions can be adhesive under such settings. Moreover, it would be good that the dressings are transparent so that the skin inspection can be easier without the need to peel them off. It is also mentioned that the education and training regarding MDRPUP can be more.

5.1.2 Patients’ Parents
Since the neonatal patients themselves are unable to express their thoughts, their parents with the special attachments, are an essential customer segment to gain direct perspectives. This interviewee is a father of a 2-year-old pediatric patient from Sweden, who was born prematurely (about 32 weeks of gestation), and has been receiving nCPAP treatment due to apnea, and hydrocephaly and its complications. The Empathy Map for this customer segment is shown in Figure 10 with picture source from Clker.com (2011).
Think & Feel: the father perceives that dressings must never be an extra trouble, since the most important task is to wear devices to sustain lives, and if the dressing is too troublesome to handle, it will cause an extra mess on daily basis, especially when the masks must be put on immediately. He wishes to find the masks that suits the best earlier so his kid could suffer less, since an unfitting device could distort the face and head especially for kids that are under development. It can be observed that the kid hates the nCPAP mask when his father is trying to put it on. The father and his wife have experienced both physical and emotional stress, since they have given a lot but still are not sure whether his son could grow up like other kids, but they choose to be strong to go through this.

Say & Do: the young couple have been caring their sick child right after birth, and most of the time at home. They barely use any dressings at home, since they are not convenient enough to handle, so they have been trying to seek the perfect mask that fits well and does not cause MDRPUs. Apart from nCPAP treatment, his son must rely feeding machines to eat, which functions of fixation are important. Moreover, the couple have to watch the night in turn, and go back and forth to get the CPAP machine from hospital every early morning, and many more.

See & Hear: After his son’s birth, he has been communicating and sharing information with other patients’ families and nurses, which has helped his son a lot. It has also been mentioned that there are always red marks left on the face, but not a wound so far, the reason can be they’ve been changing masks and found a fitting one.
**Pains**: the dressings are not easy to manage as mentioned, and the devices must be held very tightly to sustain lives which produces more pressure. No matter how good the masks are, there are always marks left, which is an early indicator for MDRPUs. Fixation tapes drop easily, and it’s painful when removed. Of course, the uncertainty about his son’s health in the future is another huge pain inside the father’s heart.

**Gains**: a perfect sealing and combination among devices, dressings and faces are important. The dressings must be intuitive and easily applicable with a wide size and shape range. Since infants’ are very tiny, the product design must be accurate to avoid mistakes, such as blocking the air ways. Since it is mentioned that the conditions in neonatal incubator and the NICU are very humid, it is significant that such dressings or fixation solutions can be adhesive under such settings. Moreover, it would be good that the dressings are transparent so that the skin inspection can be easier without the need to peel them off. It is also mentioned that the education and training regarding MDRPUP can be more.

5.1.3 Hospital Purchasers

Two purchasers have been interviewed in Sweden, one for nCPAP devices, the other for dressings. Although this customer segment does not interact directly with MDRPUP issues, they have knowledge about the accepted standard for products and decision makings, they are also a very important customer segment with a more objective and holistic view on MDRPUP. The Empathy Map for this customer segment is shown in *Figure 11* with picture source from Dreamstime.com (n. d.).

![Figure 11. Empathy Map for Hospital Purchasers](image-url)
Think & Feel: the nCPAP purchasers think devices have improved these years, but still there are no effective ways to prevent MDRPUs. And the majority of products are for adults, so there should be more products with smaller sizes specifically designed for small children. The importance of prevention is very high, and there occurred few severe wounds these years due to the work of prevention. Price is not a big problem as long as the products have good performance.

Say & Do: the purchasing process goes as follows: first the purchasers gather product information from companies; then they assemble all the needs and requirements form nurses; then the product samples are tested by a group of 8-10 nurses and purchasers in hospitals; finally, they select the best ones, and the purchasing decision are made. The purchasing happens every 2 years, and there are also 2 option years thereafter during which products can be changed according to feedbacks. All the products are purchased for every size the company offers, but not for children in particular. Hospitals cover all the purchasing expenses in Sweden.

See & Hear: advices and feedbacks from nurses on product performance have big influences on the purchasing decision, since they are facing patients on a daily basis and have more insights on which one to choose. There is an internal healthcare report system within the region, called MedControl in order to improve the healthcare quality. However, there are no big errors reported about MDRPUs, one reason is the use of prevention methods, the other is due to high workloads nurses have so only severe errors will be reported.

Pains: the edges of nostrils are easily injured due to the uneven pressure by the air flow. Another problem is that patients all look differently, as they are many patients from other parts of the world as well, their nose structure are all different. So nurses have to choose the most suitable one for each, and purchasers must consider the product variety, which all take much effort.

Gains: a good combination between devices and dressings are important to have, so they can fit better and hopefully easier to handle. As skin of infants are vulnerable, and their sizes are much smaller comparing to products for adults, so products specifically designed for infants or children are needed. Some accessories like bendings and shackles are good to make one product with wider size ranges. Dressings with customized or pre-made shapes are more convenient for nurses to put on, without the need to cut them.

5.2 Scientific Findings
This subsection provides a scientific view on the values the MDRPUP solution should possess. These perspectives are gained from company resources, and scientific literature study regarding the skin type of infants.

According to a questionnaire answered by a scientific resource of the company, it is essential to have an appropriate thickness- not too thick for being compliant to the skin curves, neither too thin in order to relieve pressure. Generally, a thickness around 4 mm is deemed optimal. Furthermore, it is important that the dressings are breathable to transfer the outer environment conditions (i.e. moisture, temperature) to the skin, and vice-versa. It needs a maximum level of adhesion without further damage to the skin when removed, in such way, good stay-on ability can be ensured and friction can be reduced. In addition, due to infants’ immature skin barrier, dressings must contain non-toxic, non-irritant substances or agents.

Moreover, according to Hoath & Maibach (2003), the pH of neonate skin will drop from 7 to approximately 4.5 right after birth till 4 weeks, as result of stratum corneum barrier development. This process is called Acid Mantle. Therefore, the dressings must not disturb such transformation as protection from harmful bacteria. In other words, the dressings must not alter such skin pH, and alkaline materials should not be used.
Moreover, skin moisture level decreases right after birth due to Trans-Epidermal Water Loss (TEWL), then increases as the skin barriers develop which can protect skin from losing water (Visscher & Narendran, 2014). Therefore, it can be observed from the scientific findings that the MDRPUP solution must support a balanced skin hydration: to transfer out the excessive moisture- 4-80 g/m²/hour (Visscher & Narendran, 2014) from skin surface to avoid maceration; to allow water from outer environment to get in, since the skin needs water to develop; meanwhile, not to absorb moisture from the skin inside, to support skin barrier development. The skin of neonates or infants is like a sponge, which is easy to lose water, as well as to absorb everything on top of it, since their skin barriers are not complete. In addition, the NICU conditions are kept with temperature around 28°C, and relative humidity are from 50% to 60% (Chirinian et al., 2012), which falls within the range of incubator conditions (temperature from 27 °C to 35 °C; relative humidity from 50% to 95%) as described above. Therefore, the performance needs to stay stable under both conditions.

5.3 Customer Surveys
Both customer insights and scientific findings are combined and translated into the Pain Relievers & Gain Creators as the outcome of first round data collection shown in Figure 12. All the 23 Pain Relievers & Gain Creators can also be referred as 23 outcomes in the theory of ODI, which serves as the input for the second round research.

![Figure 12. Pain Relievers & Gain Creators](Image)
In order to prioritize these findings shown in Figure 12, and create an optimized value proposition with the highest opportunity, a quantitative customer surveys containing all the 23 outcomes has been handed out among one neonatal department in Sweden, with 8 responses. Each outcome is rated by participants with its importance and satisfaction from 1 to 5 as low to high, and the opportunity score of each outcome can be calculated with the respective mean value of each dimension, through the Opportunity Algorithm: \( \text{Opportunity} = \text{Importance} + (\text{Importance} – \text{Satisfaction}, 0)_{\max} \) as stated above. The results of customer surveys and opportunity scores are summarized in Table 2.

**Table 2. Results of Customer Surveys & Opportunity Scores**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Importance (1-5)</th>
<th>Satisfaction (1-5)</th>
<th>Opportunity (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Product variety for small children</td>
<td>3.8</td>
<td>2.6</td>
<td>5.0</td>
</tr>
<tr>
<td>b. A good combination of devices and dressings</td>
<td>3.8</td>
<td>2.4</td>
<td>5.2</td>
</tr>
<tr>
<td>c. Devices with various shapes, sizes, and flexible size adjustment</td>
<td>4.1</td>
<td>3.0</td>
<td>5.3</td>
</tr>
<tr>
<td>d. Dressings with simple operating procedures</td>
<td>3.6</td>
<td>3.0</td>
<td>4.3</td>
</tr>
<tr>
<td>e. Dressings with appropriate thickness (not too thick for being compliant to skin, not too thin for relieving pressure)</td>
<td>4.3</td>
<td>3.3</td>
<td>5.3</td>
</tr>
<tr>
<td>f. Effective fixation solutions with superior adhesive and removing abilities</td>
<td>4.3</td>
<td>2.8</td>
<td>5.8</td>
</tr>
<tr>
<td>g. Enable re-usability and cleansing</td>
<td>2.7</td>
<td>3.2</td>
<td>2.7</td>
</tr>
<tr>
<td>h. Dressings with long use duration (7-10 days)</td>
<td>2.5</td>
<td>3.0</td>
<td>2.5</td>
</tr>
<tr>
<td>i. Pressure ulcer prevention deep inside nose</td>
<td>2.8</td>
<td>1.8</td>
<td>3.8</td>
</tr>
<tr>
<td>j. Ability of devices to monitor airflow &amp; skin conditions</td>
<td>3.7</td>
<td>2.5</td>
<td>4.9</td>
</tr>
<tr>
<td>k. Dressings with good adhesive ability under humid conditions</td>
<td>4.5</td>
<td>2.1</td>
<td>6.9</td>
</tr>
<tr>
<td>l. Dressings that can protect skin from bacteria (conform to acid mantle, pH=4.5-7)</td>
<td>4.5</td>
<td>2.5</td>
<td>6.5</td>
</tr>
<tr>
<td>m. Transparency of dressings to enable easier skin inspection</td>
<td>3.8</td>
<td>2.8</td>
<td>4.8</td>
</tr>
<tr>
<td>n. Dressings that can transfer and maintain thermal conditions from external environment</td>
<td>3.3</td>
<td>2.7</td>
<td>3.9</td>
</tr>
<tr>
<td>o. Dressings that can provide/transfer mild moisture to the skin that needs water</td>
<td>3.8</td>
<td>2.3</td>
<td>5.3</td>
</tr>
<tr>
<td>p. Dressings with stable functions (pH, adhesiveness, removing ability, moisture management, etc.) under 50-95% humidity and 25-40°C temperature</td>
<td>4.4</td>
<td>1.9</td>
<td>6.9</td>
</tr>
<tr>
<td>q. A good seal between devices &amp; dressings to reduce gas leakage</td>
<td>4.0</td>
<td>2.5</td>
<td>5.5</td>
</tr>
<tr>
<td>r. Dressings that are soft &amp; smooth, with natural, non-toxic, non-irritant substance</td>
<td>4.9</td>
<td>2.9</td>
<td>6.9</td>
</tr>
<tr>
<td>s. Dressings with pre-made, standardized shapes &amp; sizes for different areas (especially around the nose) without need of cutting</td>
<td>4.3</td>
<td>2.1</td>
<td>6.5</td>
</tr>
<tr>
<td>t. Dressings that never absorb moisture from the skin, since skin needs water</td>
<td>3.9</td>
<td>2.5</td>
<td>5.3</td>
</tr>
<tr>
<td>u. Dressings that can take out extra liquid to avoid skin break-down</td>
<td>4.0</td>
<td>2.8</td>
<td>5.2</td>
</tr>
<tr>
<td>v. Dressings that can be easily removed without skin damage</td>
<td>4.9</td>
<td>2.1</td>
<td>7.7</td>
</tr>
<tr>
<td>w. Dressings that can reduce friction with good stay-on ability</td>
<td>4.5</td>
<td>2.6</td>
<td>6.4</td>
</tr>
</tbody>
</table>
6 Analysis

As shown in Figure 12, the Pain Relievers & Gain Creators integrates both customer insights and scientific inputs, which is the primary analysis outcome. Thereafter, a second round data based on such Pain Relievers & Gain Creators has been collected through customer surveys as in Table 2, in order to prioritize such data and target on the most demanded value. This chapter provides an in-depth analysis utilizing these data and theoretical frameworks, to make sense of the second round data, and translate it further into desired outcomes.

6.1 Opportunity Analysis

In order to optimize the value intended to create for customers, an opportunity analysis based on ODI is conducted. Based on the results shown in Table 2, these outcomes are positioned into the model of Opportunity Landscape introduced previously, as shown in Figure 13.

Figure 13. Opportunity Analysis

7 outcomes are marked in white colour with an opportunity score from 1 to 5. These outcomes have covered both the “Overserved” and “Appropriately Served” categories, which means either they are very well satisfied already, or the competition regarding these outcomes are high. Therefore these outcomes marked in white colour are referred as supporting outcomes, which could be realized in a cost-efficient way, or left as an open choice for the company with their own preference and convenience. For example, in terms of the outcome g and h- “enable reusability and cleansing” and “increase use duration” which fall into the “Overserved” category, there are currently existing products that can be reused for longer time and cleaned many times such as DERMAPAD. However, it does not really matter for customers whether it’s for single
use or re-use, nor it’s for 3 days or one week, although price might differ, but as long as the solution can serve the prevention purpose, it’s fine. Thus, the developers could make their decisions regarding these outcomes or product features, depending on their own competence and understanding of the solutions they intend to create. Moreover, in terms of the outcome d- “create dressings with simple operating procedures” in the “Appropriately Served” category, though it’s important to save time, this outcome is also well satisfied since operating procedures such as taking off packages, cleansing, etc. of the dressings currently exist are not complicated, and can never be too complicated either. Thus, this outcome is good to have but should not be the key value the solution can provide. Additionally, regarding the issue of simplicity, the “adjacent” aspect such as the outcome s- “create dressings with standard and pre-made sizes and shapes” in the “Underserved” category is much more embraced by customers, and should be put more focus on comparing to outcome d. Therefore, these outcomes are regarded as supporting values intended to create for customers.

There are 16 outcomes fallen into the “Underserved” category, which suggests a large market need for such outcomes or product features, therefore these outcomes are the ones the MDRPUP solutions should emphasize on. Among them, 9 outcomes have achieved scores between 5 and 6 as marked in the green colour. These outcomes are regarded as differentiating values, which could provide distinguished product features comparing to competitors. For instance, the outcome t- “eliminate absorbing water from the skin” could prevent driving the water from skin inside, which is essential because the skin barriers of infants are not developed and thus easy to lose water, but meanwhile they need water for skin hydration. This outcome will successfully differentiate the future solution from its competitors such as Duoderm® according to customer interview findings.

Moreover, among the 16 underserved outcomes, there are 7 that have achieved the highest scores- between 6 to 9, which are marked in yellow. These outcomes represent the highest opportunity with the most important but least satisfied values, thus are the one core values the solution should offer. For example, the outcome v- “enable easy removability without skin damage” is rated the highest with the opportunity score of 7.7. As stated in the interview outcomes, many dressings can peel off skin tissues when removed, and cause a second skin damage with pain, especially for infants as they have the tenderest and vulnerable skin type. Due to this, caretakers may even try to enlarge the dressing exchanging time span just to reduce such skin damage to the minimum. If the outcome v could be realized, it will solve this very problem and create much value for the caretakers and patients. Moreover, as described before, the environment of NICU and incubators are featured with very high relative humidity (50%-95% in incubators), under which, many dressings or fixation solutions cannot stay on the skin, and cause friction or even airway blocks. Thus, the outcome k- “Enable good adhesiveness under humid conditions” is another core value demanded by customers.

In such way, the outcomes have been prioritized by the choice of customers into the three categories, and different strategies regarding the value proposition can be applied for each category as suggested above.

### 6.2 Value Proposition

By integrating and interpreting the aforementioned outcomes in the same category, the complete value proposition can be found in Appendix C, which consists of 5 core values, 7 differentiating values and 7 supporting values. It can be observed that most of these values proposed are for dressings, in which the company has much expertise. Thus, these values proposed altogether contribute to a superior and comprehensive MDRPUP dressing solution for infants less than 1 year old receiving nCPAP treatments, by applying it between the skin and device, which can reduce both patient pain and hospital cost. Since the core values are the ones with the highest opportunity to win over customers and the market, they are introduced with more focus in this subsection, as highlighted in Table 3. So far, this work has entered the stage of Products & Services regarding the model of VPD, by defining the initial value proposition.
Explanations on each core value are shown as follows. Regarding C1, it is mentioned that current dressing or fixation solutions peel off skin tissues when removed, which adds in extra pain and risk for skin injury. Therefore, this value proposed can prevent such skin damage by using silicon materials rather than hydrocolloids or gauze, and enable caretakers to removing the dressings easily with single hands since the amounts of time and people are limited as mentioned. For C2, it is essential for dressings to stay adhesive under highly humid conditions in order to avoid friction; as the skin inspection takes place every 1 to 3 hours, the dressings must be re-applied after the skin inspection; not only the adhesiveness, but also other functions must be able to remain their performance under the thermal conditions of 25-40°C as normally in the NICU and incubator setting. In terms of C3, since the infant skin may easily absorb agents on top of it due to their undeveloped skin barriers, any irritant or toxic agents or materials must be prohibited. Regarding C4, it would be a much appreciated value for caretakers if the dressings could be customized and pre-made into different shapes and sizes without the needs of cutting, so that they can apply it quickly to save time, which can be life-saving under urgent conditions; and the design needs much accuracy, since the size of an infant face is too small for any mistakes. In terms of C5, the substances the dressing has need to assist in protecting from bacteria with slightly acid pH, and must not disturb the acid mantle process as mentioned; any alkaline materials or agents should be prohibited. To conclude, these five core values altogether has shaped the future products from perspectives of skin contact, friction, microclimate, substance, and shapes, which are much demanded but barely focused by existing products as seen in chapter 2. Thus, these core values are the key aspects the future MDRPUP solution should emphasize on, and can receive very positive market response as reflected by the methodology that seeks genuine customer insights and optimizes the value proposed.
Table 3. Value Proposition- the Core Values

<table>
<thead>
<tr>
<th>Value No.</th>
<th>Outcome No.</th>
<th>Value Proposition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>v</td>
<td>To minimize skin damage when removed</td>
<td>Without peeling off any skin tissues; can be handled with single hand</td>
</tr>
<tr>
<td>C2</td>
<td>k, w, p</td>
<td>To remain good stay-on ability/ adhesiveness under humid conditions</td>
<td>Withstand high humidity in NICU and incubators: 50%-95%; allow for skin inspection every 1-3 hours; Stable performance under 25-40℃</td>
</tr>
<tr>
<td>C3</td>
<td>r</td>
<td>To eliminate use of toxic/ irritant agents or materials</td>
<td>Infants’ skin is highly susceptible/ absorptive to agents, due to their immature skin barriers; so use of any agents must be with great caution</td>
</tr>
<tr>
<td>C4</td>
<td>s</td>
<td>Allow for customization with pre-made, standardized shapes &amp; sizes without need of cutting</td>
<td>In order to minimize the application time of caretakers, especially when the devices needs to be put immediately; the product design must be accurate since infants’ faces are too tiny</td>
</tr>
<tr>
<td>C5</td>
<td>l</td>
<td>Protect skin from harmful bacteria</td>
<td>Neonates must go through acid (pH drops from 7 to approx. 4.5) for 2-4 weeks to protect from bacteria, thus, dressings must conform with such transformation, containing beneficial substances (i.e., lactobacillus, vernix); no alkaline substances</td>
</tr>
</tbody>
</table>

6.3 Risk Analysis

After defining the value proposition, a joint workshop has been conducted between the department of R&D and Marketing in the company, to evaluate the risk for developing the future MDRPUP solution based on the proposed values. The quantitative questionnaire shown in Table 1 has been fulfilled with consensus, based on which the probability of success can be positioned with a score of 20 in the Products & Services axis, and a score of 7 in the Market & Customers axis, as shown in Figure 14 (copyright by Adj. Prof. Bengt Järrehult). Due to confidential reasons, the specific scores for each measurement of the questionnaire have been reversed within the scope of the company, instead the final result is presented as shown below.
It can be observed from Figure 14, the probability of success for developing such MDRPUP solution is 50% to 60%, with adjacent products & services, and similar market & customers as the company currently possesses. It also means this future product is neither too safe as what the company has now, nor too risky as a completely different type of product and market. The market & customers axis is deemed similar as now, since the company has already started to sell some other MDRPUP solutions for other anatomical sites, thus the resources such as sales channels and customer insights are already established. However, as none of the products sold are for infants with nCPAP treatment, the product requirements and design needs adaption but still not entirely new to the company, which is why the product & services axis is adjacent.

In addition, it is more likely to succeed with adjacent product & services in a known market & customer segments, rather than the other way around, as it can be observed from the chart that the change of probability on the products & services axis is slower than the market & customers axis. This is due to the reason that it's always easier to innovate on the products with well investigated market conditions, known customer insights, and predictable customer behaviours, rather than to promote similar products across different market segments without established resources and expertise. Moreover, this innovation could also be categorized in to the type of Adjacent Innovation by Nagji & Tuff (2012). To summarize, this MDRPUP future solution possesses a high probability of success, with sufficient resources possessed by the company regarding market and customers, but the future products need more adjustment to what the company currently has, according to the value proposition above.
7 Discussion

In this chapter, perspectives from theories and data, as well as analysis are discussed further in order to make a thorough understanding, and draw a solid conclusion.

As stated previously, the theory of LCD as the backbone of the theoretical framework, suggests to start with “learning” to gain an overall picture about markets and customers first before trying to build the solutions, so that risks and costs can be reduced. This work has followed this principle by starting with MDRPUP background study, and market reviews including investigating in customer base, nCPAP market potentials, and the products from competitors. This starting point turns out to be beneficiary for later data analysis, since it has provided essential understanding of MDRPUP, evidence to succeed for a promising business opportunity, and also a picture regarding current nCPAP and dressing markets. These learning outcomes has assisted in further steps when designing hypothesis and interview guides, making them more accurate and specific.

Moreover, the LCD promotes an iterative process- “keep learning” when investigating customer insights and defining values, which is also reflected in this work by the second round customer surveys guided by ODI to optimize the values. There are 23 Pain Relievers and Gain Creators found after the first round of customer interviews, however, no value proposition can solve every concern customers have, considering the factors of cost and technology feasibility as well as the value as a product niche. Therefore, these 23 Pain Relievers and Gain Creators/Outcomes have been regarded as inputs for customer surveys to evaluate which of them possess the highest opportunity. In such way, the value proposition can be presented in a prioritized way with categories of core, differentiating and supporting values with different strategies to apply.

Furthermore, the framework of VPD provides a pragmatic way of seeking customer insights and creating values, with clear steps to follow and the emphasis on Jobs, Pains and Gains. As stated above, this aspect is well aligned with the thinking of ODI, which emphasizes on the “jobs to be done” and driving force of the outcomes (referred to Jobs, Pains and Gains in the theory of VPD), instead of their direct advice on solutions. The common reason is the fact that the genuine customer insight lies beneath their words, but the way they accomplish their jobs, problems they face, and welfare they wish for. Thus, when designing interview guides and conducting interviews, the implicating questions regarding solutions have been avoided, rather the topics of interviews have been focused on the Jobs, Pains and Gains as direct inputs, to ensure the application of theoretical framework of VPD initiates in a clear structure.

It can be observed that the theories and models of LCD, VPD, ODI as well as the Empathy Map, Risk Matrix used can be perfectly combined to serve as a strong and comprehensive tool in terms of digging customer insights and designing value propositions. In this certain circumstance, the theoretical framework designed has demonstrated a perfect fit by serving the common goal from different perspectives and functions: the LCD provides an overall structure with its five steps; the Value Proposition Canvas by VPD presents a specific method on how to collect genuine customer insights and create value accordingly; the Opportunity Landscape by ODI strengthens the values collected with optimization and tailored strategies; the Empathy Map serves as a tool for summarizing interview outcomes from various perspectives regarding not only what they say and do, but also how they feel, what they think, have seen and heard, all of which are aligned with VPD; and the Risk Matrix offers an estimation about the probability to succeed after defining the value proposition, based on the familiarity the company has regarding both market and product dimensions. Only with such solid theoretical support, a thorough understanding of customer and scientific insights can be gained, and a comprehensive value proposition can be designed accordingly.
Regarding the methodology of this research, guided by the theoretical framework, research method has collected relevant and valid data for further analysis and conclusion. 8 qualitative interviews have been conducted with 3 different customer segments to collect insights with a broad view: the nurses/healthcare professionals are the ones that cope with MDRPUP directly, with much expertise and passion regarding this concerning issue for infants in particular; patients’ parents have even more emotional attachment to this issue, and also have MDRPUP experience through home care; the hospital purchasers are responsible for treatment and dressing purchasing, and interact much with nurses, thus their views are also important. Moreover, by comparing the 6 face-to-face interviews conducted in Sweden, 2 phone interviews to China as well as indirect customer insights from the US, it can be seen that the issue of MDRPUP is universal. Although the two countries have different healthcare systems, the findings indicates a global need. Furthermore, the quantitative customer surveys with 8 responses in a neonatal hospital department have ranked the values numerically, which has well complemented the qualitative interview research method. In addition, another quantitative questionnaire from Risk Matrix has assisted estimating the probability to succeed with the future solution, by nailing the numeric scores in both Market & Customers, and Products & Services in the Risk Matrix, which from a quantitative perspective makes the business case more solid for the issued company. Thus, it can be concluded that the mixed research method can be easily adapted to this setting.

From the view of the customers, this value proposition offers a unique product niche of MDRPUP for infants with nCPAP in particular. Apart from the existing products, it not only serves the purpose of pressure redistribution, but also skin contact, microclimate, friction, etc., from the prevention perspective rather than treatment. From the standing point of the company, it offers a new product niche within the MDRPUP solution portfolio, meanwhile the established expertise in dressings can also be leveraged. By transferring the value proposition defined in this work, the product portfolio can be expanded into other medical devices (i.e., tracheostomy, casts, and cervical collars) for other populations (older pediatrics, adults, etc.). As the infant skin is the most vulnerable type, the knowledge acquired for this population with the gentle solution can be transferred to other age groups, which cannot be reversed. Moreover, as customers perceive dressings as “something extra” attached to the device and the best situation would be “perfect devices with no need for anything extra”, the markets left for dressings to a large extent depend on the performance of devices that sustain patients’ lives. In addition to constantly improve the device performance, the device manufacturers have also started to integrate the device-dressing solutions as mentioned in the chapter of Market Review, although they are far from the perfect, still has put a risk on dressing manufacturers. Thus, apart from a higher product standard for dressings, it will be beneficial to for the company collaborate with the respective device manufacturers for joint MDRPUP solutions from a long perspective, with stronger bargaining power due to established dressing expertise. Once this collaboration takes place, it will add in more dynamics to the MDRPUP market within the healthcare industry, and this new step of solution integration will bring competitive advantages for issued companies, and welfare for customers.
8 Conclusion

To conclude, this research work presents a comprehensive value proposition for a MDRPUP solution for infants less than 1 year old receiving nCPAP treatment. By applying and integrating several theories and models, the empirical data regarding market conditions, customer insights, gained from both qualitative and quantitative methods can be analysed and discussed under a solid basis. Based on this research work, it can be concluded that the proposed business possess a promising opportunity by serving the genuine need of over 1.3 million neonatal patients per year across 14 countries; the integrated theoretical framework performs effectively when it comes to customer development and value proposition design, as proved under a healthcare setting in this research; the value proposed in this work offers customers great welfare, provides the company with solid inputs and suggestions on further steps, and sheds light on the healthcare industry for future research and innovation regarding MDRPUP issues.
Acknowledgement

The successful completion of this research work is dedicated to many scholars, professionals, and external partnerships. The author hereby in this section expresses his much respect and many thanks to all those nice people who has contributed to this research.

The adjunct professor, Bengt Järrehult from Chalmers University of Technology, has provided this research with solid theoretical base as the supervisor. Bengt has gained much insightful expertise regarding innovation management from both of his successful professional and academic career. He has kindly passed on his knowledge and theoretical tools through regular meetings and contacts, which adds in an indispensable support for a convincing and organized work. Moreover, Bengt also has an easy-going and fun personality, which makes every moment fun and rewarding. Therefore, the author first of all, would like to expresses his many thanks and admiration to Bengt for his much contribution.

Moreover, Joakim Björkdahl, the associate professor from Chalmers University of Technology has provided much valuable advice in terms of both the contents and its presenting, as the examiner of this thesis work. Moreover, as the thesis opponents, Kristina Lahdou and Adam Hill have also contributed their time and efforts to give much advice on the content organizing, academic writing, etc. Thus, the author wants to thank Joakim, Kristina and Adam for their constructive advice, and Angelica Linnehav for her administrative assistance, without which the work would not be as complete as it is today.

In addition, the author would like to thank all the professionals from the company this research collaborated with, as well as the external partnership, especially Mats Fridh from Innovationsslussen, a healthcare innovation sector, who has kindly devoted his time and efforts for the customer interviews. They have offered the author much assistance in various areas such as interview contacts, scope setting, administration, market research, and data analysis. The author greatly appreciates all the efforts from the collaborated company and its partnerships, without which this research would not have various resources and support especially in terms of empirical data.

Furthermore, the author also would like to express his many thanks to all the interviewees and neonatal nurses who have participated in the customer surveys. They have not only contributed their precious insights regarding the proposed research, but also demonstrated their responsible professional integrity as healthcare people, and the enormous and selfless love as parents.

Last but not the least, the author would like to thank the department of Technology Management and Economics, Chalmers University of Technology, Sweden, which has offered the author a joyful and rewarding journey of a two years’ study and research. The knowledge, passion, and joy shared among the teaching staffs and classmates has opened a new world of wonder for the author, where he has met a better self with an open mind, progressive collaboration and communication skills, more mature personality as well as a stronger knowledge base for future adventures. The author will always appreciate and treasure this unforgettable journey together with Chalmers, and hereby sincerely wishes all the teachers, researchers, classmates and professionals he has met with pleasure, best of the luck in their future endeavours.
References


Appendix

Appendix A. Interview Guides for Nurses & Healthcare Professionals

Hypothesis:
*I believe nurses and healthcare professionals experience problems on a lack of efficient and effective solutions on preventing Medical Device Related Pressure Ulcers (MDRPU) occurring in the head/ front neck when caring infants, thus have need for such solutions.*

Facts & Contexts:
- How often does MDRPU happen to infants? How many of all infants develop these MDRPU approximately? Common areas?
- How big is this issue comparing to your everyday struggles?

Jobs:
- Are there any tools or protocols regarding MDRPU Prevention? How is it conducted (e.g., risk assessment tools like Braden Q being used, or any other?)?
- Could you tell me how the process goes when preventing MDRPU on infants? How long does it take? Any other people involved?
- Could you list the activities that are the most important to prevent the MDRPU?
- Are there situations that take priority over preventing MDRPU? How does it look like?
- When it comes to pre-term infants (babies born before 37 completed weeks of gestation), is there anything different?
- How do you feel when you see MDRPU happening, especially to the infants (emotional and social jobs)?

Pains:
- Any tools, products, or solutions being used along the process to get the jobs done? What do you think of them (any drawbacks or advantages to mention)?
- What are the problems that bother you the most, or hold you back during the prevention processes? Why?
- How do you usually solve these problems? Any products/tools you mentioned could help? What would be good to have to solve these problems? Any features to mention?
- What are the problems that are important to deliver a desired outcome, but cannot be solved at the moment (underserved outcomes)?

Gains:
- Imagine the ideal situation where everything works perfectly, how far away is the reality from that in your opinion? Why? (The Gap)
- If you could have a magic wand and be able to do anything you can’t do today, what would it be? Don’t worry about whether it’s possible, just anything. (What’s the ideal situation; Probe products, tools, protocols, resources, etc.)

Follow-up:
- Is there anything else I should have asked, you think it’s good to know as well?
Thank you for your time, and I’m sure it would be of much help to our work. Can we come back to you if there are a few further questions?

Appendix B. Interview Guides for Pediatric Patients’ Parents

Hypothesis:
I believe pediatric patients and their parents experience excessive pain both physically and emotionally due to Medical Device Related Pressure Ulcers (MDRPU) occurring in the head/neck, meanwhile have been striving to find effective solutions.

Facts & Contexts:
- Could you tell me a bit about your child who has/had the problems of pressure ulcers caused by medical devices?
  - How old was your child when having this?
  - What kind of devices?
  - How many hours per day your kid were wearing this?
  - How long was the hospital stay?
  - Where was the ulceration site?
  - How did MDRPU happen?
  - Were there any dressings applied? What and how are they?

Jobs:
- Could you tell me how the process was like when the device was put on last time? How long did it take? Any other people involved?
- Are there any actions taken in order to prevent MDRPU in advance?
- Could you list the activities or factors that you think, are the most important to prevent the MDRPU (ask for a ranking by importance)?
- Are there situations or activities that must take priority over MDRPU prevention? How does it look like?
- How do you feel emotionally as a parent when seeing it happen to your child? I guess it must be terrible.

Pains:
- What are the problems that bothered you and your child the most, or held you back during the prevention processes? Why?
- What did you do to solve these problems? Any products/tools you mentioned could help? What would be good to have? Any features to mention?
- What are the problems that are important to prevent this from happening, but cannot be solved at the moment (underserved outcomes; ask for a ranking by importance)?
- How does this pressure ulcer affect your daily lives, I mean both you and your child? (Socially, Emotionally, Physically)

Gains:
- What could have been done better to your kid, in order to prevent MDRPU, if you got another chance?
• Imagine the ideal situation where everything works perfectly, how far away is the reality from that in your opinion? Why? How will you strive to get there? (The Gap)
• If you could have a magic wand and be able to do anything you can’t do today, what would it be? Don’t worry about whether it’s possible, just anything.
• How would you feel in the ideal world?

Follow-up:
• Is there anything else I should have asked, you think it’s good to know as well?
• Thank you for your time, and I’m sure it would be of much help to our work. Can we come back to you if there are a few further questions?
<table>
<thead>
<tr>
<th>Species</th>
<th>Value No.</th>
<th>Outcome No.</th>
<th>Value Proposition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Contact</td>
<td>C1</td>
<td>v</td>
<td>Minimize skin damage when removed</td>
<td>Without peeling off any skin tissue, with single hand</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>C2</td>
<td>k, w, p</td>
<td>Remain good stay-on ability/adhesiveness under humid conditions</td>
<td>Withstand high humidity in NICU &amp; intensive 59%-95%, to minimize risks of unintentional drop-off which can cause friction, chafing, and airway blockage for skin inspection every 1-3 hours; all functions must perform stable under atmospheric humidity level and temperature of 25-40°C In addition, a slippery inner layer, and smooth interfaces between multiple layers help reduce friction and chafe accordingly</td>
</tr>
<tr>
<td>Substance</td>
<td>C3</td>
<td>r</td>
<td>Eliminate use of toxic/irritant agents or materials</td>
<td>Infant's skin is highly susceptible/absorptive to agents, due to their thin skin barrier, no use of any agents must be with great caution</td>
</tr>
<tr>
<td>General</td>
<td>C4</td>
<td>s</td>
<td>Allow for counteraction with pre-made, standardized shapes &amp; sizes without need of cutting</td>
<td>In order to maximize the application time of caregivers, especially when the device needs to be put immediately; the design must be accurate since infant's faces are too tiny</td>
</tr>
<tr>
<td>Microclimate</td>
<td>C5</td>
<td>l</td>
<td>Protect skin from harmful bacteria</td>
<td>Neonates must go through acid mantle right after birth due to skin barrier formation for 2-4 weeks, during which skin pH decrease from 7 to approx. 4.6 to protect from harmful bacteria; therefore, dressings must conform with such transformation, containing beneficial substances (e.g., lactobacillus, vitamin A, alkaline substances)</td>
</tr>
<tr>
<td>Microclimate</td>
<td>D1</td>
<td>u, a, t</td>
<td>Allow for moisture breathability</td>
<td>Transfer out excess moisture from skin surface (from 2 to 85%); due to Triticale to avoid skin dehydration; bring in a mild level of moisture (as the outer condition 50%-90% RHI) to facilitate skin hydration; never absorb moisture from the skin</td>
</tr>
<tr>
<td>Pressure</td>
<td>D2</td>
<td>e</td>
<td>Minimize pressure through soft &amp; elastic materials with a modest thickness level</td>
<td>Not too thin for being able to off-load pressure; around 0.5-0.6cm is appropriate</td>
</tr>
<tr>
<td>Bakteriostasis</td>
<td>D3</td>
<td>a</td>
<td>Allow for product variety specifically for small children</td>
<td>In terms of sizes, shapes for different anatomical sites (nose, chin, forehead, ears, cheek around nose)</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>D4</td>
<td>b</td>
<td>Allow for a data-dripping combined solution</td>
<td>Dressings must conform to device performance, and a joint solution with dressings attached to devices is more easily to handle for caregivers</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>D5</td>
<td>f</td>
<td>Allow for effective friction solutions with rupture adhesive &amp; removing abilities</td>
<td>Apart from dressings, performance of fracture tape has never been good enough for neonates, regarding adhesive and easily-removed abilities</td>
</tr>
<tr>
<td>General</td>
<td>D6</td>
<td>q</td>
<td>Allow for a good seal between devices &amp; dressings to reduce gas leaks</td>
<td>Apart from being adhering to the skin, dressings must stay with or in the devices as well. Skin dressing device must conform with each other</td>
</tr>
<tr>
<td>General</td>
<td>D7</td>
<td>r</td>
<td>Enhance device variety with shapes, sizes, and flexible size adjustment</td>
<td>This function is from the device perspective; targets to use fit for different age groups and different looking faces</td>
</tr>
<tr>
<td>Appropriate</td>
<td>S1</td>
<td>m</td>
<td>Allow for transparent dressings to enable easier skin inspection</td>
<td>Skin inspection every 1-3 hours, it would be easier to be able to look through the dressings to inspect skin</td>
</tr>
<tr>
<td>Overued</td>
<td>S2</td>
<td>n</td>
<td>Transfer and maintain thermal conditions from external environment</td>
<td>With temperature range approx. 25-46°C</td>
</tr>
<tr>
<td>Supporting</td>
<td>S3</td>
<td>j</td>
<td>Enable skin conditions &amp; airflow monitoring</td>
<td>A device like a sensor that can monitor skin conditions (temperature, moisture, pH, etc.) and airflow</td>
</tr>
<tr>
<td>Supporting</td>
<td>S4</td>
<td>i</td>
<td>Enable inspection and prevention of intranasal pressure ulcers</td>
<td>There are no effective solution for PUs deep inside the nose for neonates currently, due to the small size of their noses</td>
</tr>
<tr>
<td>Supporting</td>
<td>S5</td>
<td>d</td>
<td>Allow for simple operating procedures</td>
<td>Apart from customization, other parts such as packaging, cleansing (if applicable) must be simple</td>
</tr>
<tr>
<td>Supporting</td>
<td>S6</td>
<td>g</td>
<td>Enable re-usability and cleansing</td>
<td>The dressings are reusable for single person after cleansing</td>
</tr>
<tr>
<td>Supporting</td>
<td>S7</td>
<td>h</td>
<td>Increase use duration (7-10 days)</td>
<td>Keep all functions within the use duration</td>
</tr>
</tbody>
</table>