Application of an Early HTA Framework for Determining Potential Cost-effectiveness and Value of a Medical Device

The Case of the Ably Bed

Agnes Karina Straum

Supervised by Eline Aas

Master Thesis
Department of Health Management and Health Economics

UNIVERSITY OF OSLO

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Written by: Agnes Karina Straum

Supervised by: Eline Aas

Thesis submitted as a part of the Master of Philosophy Degree in European Health Economics and Management

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http://www.duo.uio.no/
Abstract

Background: The high speed of innovation of medical technologies are argued to be an important driver of health care costs. There is an ongoing shift from volume to value-based health care, and HTA plays an important role in this process. Ably Medical is developing a fully electronic hospital bed designed to improve care and rehabilitation. Ably Medical and the Ably Bed was used as a case study in the thesis.

Objective: The aim of this thesis was to apply a framework for early HTA, with the objective to inform Ably Medical about their technology’s potential for being cost-effective.

Methods: Three different analyses were conducted as part of an early stage HTA of the Ably Bed and its impact on the risk of pressure ulcers. A decision-tree model was developed, and a cost-utility analysis was conducted. A headroom analysis was performed to calculate the headroom for cost-effectiveness and value of sales net of production costs. Interviews with key stakeholders of Ably Medical provided information about the procurement process of medical technologies, the issues related to prevention of pressure ulcers and the technology of the bed.

Results: The result from the cost-utility analysis indicated that the Ably Bed in combination with common practice for prevention is cost-effective compared to common practice alone. There are however, substantial uncertainty surrounding the result. The Headroom analysis showed that there is a headroom for cost-effectiveness. The interviews revealed that procurement is competition based, and price is the main factor for decision making.

Discussion: Lack of data on the Ably Bed limits the analyses. Headroom estimates are normally overestimated. The threshold for cost-effectiveness (WTP per QALY) used in the analysis was fairly low. The results from the analyses would have been more robust had a higher threshold been applied.

Conclusion: By the application of the early HTA framework, the thesis found that the Ably Bed has a potential for being cost-effective. The research of the thesis demonstrates that early HTA is feasible, and it is recommended that developers of medical technology use the framework to assess commercial viability, early on in the development process, to improve the likelihood of success in the market.
Acknowledgment

I would like to thank my supervisor, Eline Aas. She has been of great help from the early planning process and throughout the project work. Her patience, guidance and support have been of great importance, and have kept me motivated even through times when I believed this project would not be feasible.

I am very grateful for my employer, Ably Medical AS and my colleagues, who have been understanding and given me time to focus on my thesis. I am very much looking forward to taking on new challenges at Ably Medical after graduating.

I would also like to give a big thanks to my boyfriend, Jakob, who has been patiently keeping up with me during stressful times. Thank you for always listening, sharing your knowledge and giving me motivation and confidence when needed. Thank you for being my editor!

Finally, I would like to thank my family for always supporting and believing in me. To my mom and dad, thank you for being the great people that you are and for patiently waiting for me to come home and visit. I am looking forward to spending more time together this summer!

Agnes Karina Straum

June 2018
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AE</td>
<td>Adverse event</td>
</tr>
<tr>
<td>CEA</td>
<td>Cost-effectiveness analysis</td>
</tr>
<tr>
<td>CEAC</td>
<td>Cost-effectiveness acceptability curve</td>
</tr>
<tr>
<td>CUA</td>
<td>Cost-utility analysis</td>
</tr>
<tr>
<td>DRG</td>
<td>Diagnosis-Related Groups</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross domestic product</td>
</tr>
<tr>
<td>HAPU</td>
<td>Hospital acquired pressure ulcer</td>
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<tr>
<td>HCC</td>
<td>Health care costs</td>
</tr>
<tr>
<td>HrQoL</td>
<td>Health-related quality of life</td>
</tr>
<tr>
<td>HTA</td>
<td>Health technology assessment</td>
</tr>
<tr>
<td>ICER</td>
<td>Incremental cost-effectiveness ratio</td>
</tr>
<tr>
<td>LOS</td>
<td>Length of stay</td>
</tr>
<tr>
<td>MRP</td>
<td>Maximum reimbursable price</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute of Health and Care Excellence</td>
</tr>
<tr>
<td>NMB</td>
<td>Net monetary benefit</td>
</tr>
<tr>
<td>PSA</td>
<td>Probabilistic sensitivity analysis</td>
</tr>
<tr>
<td>PU</td>
<td>Pressure ulcer</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality-adjusted life-year</td>
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<tr>
<td>WTP</td>
<td>Willingness-to-pay</td>
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1 Introduction

In Europe, the average expenditures of health care are 10% of gross domestic product (GDP). 76.6% of these expenditures are related to inpatient and outpatient care. As much as 16.1% is spent on pharmaceuticals, and 7.3% is spent on medical devices (MedTech Europe, 2016). Measured in terms of patent applications, the medical technology industry is by far, the most innovative industry in Europe (European Patent Office, 2017). The rapid growth and high degree of innovation is claimed to impose increased costs on health care (Kumar, 2011). However, innovative technologies may have the potential for disrupting health. New technologies may not only improve the quality of care, but also reduce costs by enabling care to be provided, both cheaper and faster (Christensen et al., 2000).

The extremely high and ever increasing expenditures in health care, have resulted in a global shift from volume-based to value-based health care (Prada, 2016). Rather than focusing on volumes and cost-constraints, health care policy makers are now more oriented towards patient outcomes of treatment and the value of those outcomes. The definition of value-based health care may be dependent on who you ask. However, if the aim is to make health care more sustainable, without compromising on quality, the definition should encompass the concept of cost-effectiveness. For this reason, the definition of health value used in this thesis is; the health outcomes achieved per dollar spent (Porter and Teisberg, 2006). By this definition, the goal is to maximize the health value for patients per dollar spent, a strategy that has the potential of making the health care systems more economically sustainable (Porter 2010).

To achieve value-based health care, a change in mindset is needed. Not only by policy- and decision-makers, but also by key stakeholders, such as the health care providers, financers and suppliers of health technology. In the field of pharmaceuticals, value-based health care is already well-established through strict market regulations and evidence-based coverage decisions, which encompasses not only the cost of drugs, but also its cost-efficiency, based on the patient outcomes and the value of those outcomes. Although new EU regulations on medical devices are ensuring a stricter control and reinforced requirements of clinical evidence (European Commission, 2017), there is still less standardization of submission of data for evaluation, and less requirements concerning the proof of cost-effectiveness compared to pharmaceuticals (Fuchs et al., 2017). Moreover, the requirements for market authorization is based on quality from an engineering perspective rather than effect for the users (Fuchs et al.,
It could seem like the decisions on whether to invest in new technology are determined on price only, neglecting the efficiency, and thereby the value for money on the investment. It can therefore be difficult for a medical technology company to determine to what extent one should invest in the assessment and evaluation of health technology, to increase the chance of technology uptake. However, incorporating methods for technology assessment from the very beginning of a development process, may improve investment decisions and ensure that only the potentially cost-effective devices are brought to the market (Vallejo-Torres et al., 2011). A question emerging is then, whether conducting technology assessment at an early stage of product development is feasible.

The aim of this thesis was to apply a framework for early health technology assessment (HTA), with the objective to guide developers, early on in the product development, about the technology’s potential for being cost-effective and successful in the market.

Ably Medical AS is a Norwegian medical technology company, founded in 2015. Although they are yet to bring their first product to market, they have been getting a substantial amount of attention for their technology. The company is developing an electronic patient bed with machine learning capabilities, designed to improve patient care and rehabilitation, by reducing the risk of patient falls and pressure ulcers, as well as reducing nurse load. The thesis work will focus on the case of Ably Medical and their product; the Ably Bed. For a start-up company like Ably Medical, resources are scarce, and decisions have to be made fast, with little to know knowledge about the actual performance of the technology, the application of an early HTA framework to assess potential cost-effectiveness is therefore considered appropriate in the case of the Ably Bed.

1.1 Outline of thesis

The thesis has been organized into seven main chapters. In Chapter 2, background information is presented to contextualize the aim and objective of the thesis. Firstly, some information related to the case of Ably Bed is presented. Secondly the issues of adverse events and pressure ulcers are described. Finally, the concept of value-based health care and its connection to cost-effectiveness and assessment of health technology is introduced.

The main concepts, and theoretical framework of HTA is presented in Chapter 3, including early economic evaluation, headroom analysis and stakeholder preference analysis.
Chapter 4 outlines the methodology of the thesis. The chapter starts by presenting the economic evaluation, and the decisions that have been made concerning the study design. Thereafter, the methodological considerations of the Headroom analysis are presented. Lastly the chapter presents the chosen method for performing and analyzing the interviews with the stakeholders.

In Chapter 5, the results from all the three different analyses are presented. For the cost-utility analysis, the base case cost-effectiveness level as well as the result from the sensitivity analysis on the parameter uncertainty are presented. Moreover, the output of the calculations of the headroom analysis are presented, as well as the findings from interviews with stakeholders.

The interpretation and discussion of the results will be presented in Chapter 6. In this chapter, the limitations of the research are discussed, along with suggestions for future research. The thesis ends with a conclusion in Chapter 7.
2 Background

Before presenting the theory behind economic evaluation, some background information on the case, Ably Medical and the Ably Bed, will be given. A major health issue that will form the basis for the technology assessment is also introduced, as well as some more information related to the concept of value-based health care and how this is connected to technology assessment.

2.1 Ably Medical and the Ably Bed

Ably Medical AS was founded by the three entrepreneurs from Ålesund, together with a professor in psychology at the University of Oslo. The company’s vision for future health care is; more human technology (Ably Medical AS, 2017). Human technology can be understood as technology designed to be user-friendly were the technology is adapted to the user, and not the other way around (Satava and Ellis, 1993). The company aims at being a major developer of medical technologies, and the first product they are working on is the Ably Bed. The patient bed is a smart bed, designed to target and improve three major issues related to patient care and rehabilitation. The issues the technology of the Ably Bed is targeting are; nurse load, patient falls and pressure ulcers (PU). Their technology is patented, but as the product is still under development, the technology and design of the product is being changed along the learning process of the development. In other words, they have adopted an agile development process, which may be beneficial, as it allows for continues improvement of the product. The company is taking part in a strategic market access program, by the Canadian innovation hub, Medical and Related Sciences, named MaRS EXCITE. The program is functioning as a bridge between innovative health companies and the health system of Ontario, Canada. According to MaRS Discovery District (2018), the goal of the program is:


They support medical technology companies through the process of gaining market access, by providing opportunities for clinical testing and thereby producing evidence of efficiency and product value (MaRS Discovery District, 2018). In May 2018, the prototype patient bed was shipped to Toronto to perform a usability study together with health care personnel from Hamilton Health Science. The purpose of the study was to gain more knowledge and a better
insight into the way health care personnel work, what needs they have regarding patient care and the environment surrounding the patient.

The beds’ key design is its longitudinal springs which allows for a more flexible movement, compared to a standard patient bed. This flexible movement redistribute the pressure on the patient’s body. The use of pressure redistribution surfaces is recommended as a way of preventing PUs (Fleurence, 2005). It is therefore very interesting to investigate how this bed can function as a device for prevention or part of the treatment of PU, only by altering the pressure points and avoiding constant pressure on typical problem areas such as tail bone, heels and shoulder blades. The springs are equipped with state-of-the-art, non-intrusive and integrated sensor technology, that measures and monitors heart rate, temperature, weight and muscle strength of the patient.

The three major issues related to patient care and rehabilitation are all of great interest from a health economic perspective, seeing as they may have impacts from a societal perspective. However, for the purpose of this thesis, the case of the Ably Bed has been focused on the bed and PUs only, leaving out both the nurse load and patient fall issues.

2.2 Pressure ulcers in a hospital care setting

Adverse events (AE) in health care can be defined as an unintended injury or complication that leads to a prolonged hospital stay, disability at time of discharge or death, caused by health care management, and not the disease itself (de Vries et al., 2008). AEs are related to the quality of care and can be an important factor for reduced patient value. Literature reviews, shows that 4 to 17 % of all hospitalizations results in AE. However, one to two-thirds of these AEs are preventable (Rafter et al., 2015).

Both patient falls and PUs can be considered an AE, moreover, Bredesen et al. (2017) argue that PUs are among the most common AEs. In her research on prevalence rates of PUs in a Norwegian hospital setting, she found an overall prevalence of 18.2%, and a prevalence of 7.2% for more severe PUs (stage II-IV). For hospital acquired pressure ulcers (HAPU), the prevalence rate was found to be 15%. The prevalence varied between the hospital wards, where the intensive care units and medical wards had the highest and second highest prevalence rates (Bredesen et al., 2015). PUs and HAPUs are not only a problem due to the reduced quality of life and reduced value it imposes to the patients, it is also a driver to the high health care
expenditures. In the UK alone, PUs has been estimated to cost the National Health Service between £1.4bn and £2.1bn each year (Fleurence, 2005).

PUs are normally described as a localized injury to the skin and the underlying tissue. PUs are categorized into different stages depending on severity. Bony parts of the body, such as the heels, elbows, shoulder blades and tailbone are especially exposed areas (National Pressure Ulcer Advisory Panel et al., 2014). Table 1 shows the different severities of PUs.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>I</td>
<td>Intact skin with non-blancheable erythema</td>
</tr>
<tr>
<td>II</td>
<td>Partial thickness skin loss</td>
</tr>
<tr>
<td>III</td>
<td>Full thickness skin loss</td>
</tr>
<tr>
<td>IV</td>
<td>Full thickness tissue loss with exposed bone, tendon or muscle</td>
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(National Pressure Ulcer Advisory Panel et al., 2014)

In their systematic review, Coleman et al. (2013) found that there is no single factor for developing PUs, but rather combinations of several determinants, where mobility, activity level and diabetes are most important. Skin moisture, age and nutrition are among other important factors. Early assessment and detection of patients at risk for developing PUs, as well as the use of preventive measures are central in the work towards reducing the risk of PUs, and thereby reducing the hospitals costs related to treatment and prolonged stays. Risk assessment can be done using a classification system such as the Braden scale. The tool was developed in the US in 1987 and uses six factors to identify patients at risk of developing PUs. Scores are given accordingly, on a range from 6 to 23, where a lower score is associated with a greater risk of developing an ulcer (Martin and McFerran, 2017). Preventive measures include repositioning of the patient on a scheduled basis, use of pressure redistribution mattresses, such as high specification mattresses, offloading of heel pressure, skin care, incontinence care, proper nutrition and the use of silk rather than cotton fabrics (National Pressure Ulcer Advisory Panel et al., 2014, Martin and McFerran, 2017, Bredesen et al., 2017). The treatment of PUs will depend on the grade of the PU and possible complicating factors. General treatment consists of a set of methods such as wound care (cleansing, debridement and dressing) as well as pain management. For the most severe cases, such as a PU of grade III or IV, surgery may be necessary (National Pressure Ulcer Advisory Panel et al., 2014)
PUs affects both patient and the health care system negatively, by reducing the health-related quality of life (HrQoL) of the patient and increases the length of stay (LOS) at the hospital due to the need for additional care, as well as prolonged rehabilitation time. For this reason, PUs are not only a problem for the patients, but also for the health care system and society as a whole, as resources are scarce, and there are large opportunity costs associated with the treatment of PUs.

2.3 Value-based health care

Health care is often referred to as an intermediate product. It is not health care per se that is of importance, but the improvement in health (Palmer and Torgerson, 1999). Thus, health care functions as a means to the end of improvement in health, which is measurable through health value. Health value is, as previously stated, defined by Porter and Teisberg (2006), as the health outcomes achieved per dollar spent. A definition which encompasses the concept of efficiency. Patient value can be defined as health outcome of care, provided to the patient (Porter 2010). Hence, efficiency is reached when we get the maximum health value out of resources spent. Increased spending in health care is not sustainable. A higher degree of efficiency however, will generate more value without increasing costs. Thereby ensuring that the society’s expectations for improvement in quality of health care is met in a sustainable manner.

The (WHA, 2007, p. 1) states that health technology is “the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives”. By this definition, health technology is developed to be used in health care and improve quality of lives.

A central part of value-based health care, is the procurement of health technology. The term, ‘value-based procurement’ is therefore trending among health care providers and developers of health technology (Prada, 2016). Value-based procurement opens up for a new type of pricing strategy, and price negotiation between the producers and health care providers. The standard approach to procurement of health technology, be it medical devices or medicine, is for a producer to set a price which the health care provider either accept or reject, and where prices are lowered until an agreement is reached (Girling et al., 2015). Value based procurement on the other hand, is an approach where the health care provider is basing the price negotiation on the added value the health technology generates. In other words, one negotiates based on the
health benefit that particular device or medicine is estimated to generate, rather than on a price based on the standard cost-plus approach. Pricing strategies based on health value, and procurement processes based on a value for money principal rather than a cost-minimization principal, may have a positive impact on the allocation of health care resources. It is however, important to acknowledge that this is a case of a double-edged sword. The price of technology may increase if the willingness to pay (WTP) is very high, and as patents ensure less competition, it may have the opposite effect on health care costs than what may have been intended.

Moreover, decision-makers in procurement following the value for money principal, can potentially make investment decisions that yields a larger return of investment, in the form of patient value, than what would otherwise be the case. This implies that, in a decision on whether to invest in one of two medical devices that are designed for the same purpose, one should not only consider the price, but also the proved effect from clinical trials, to make optimal decisions. Value-based health care is a holistic approach which has the potential of improving the conditions for both care providers, technology suppliers and patients, by ensuring that all parties have the same objective, namely maximization of patient value. Procurement based on health value allows for uptake of medical technology and innovations proved to be cost-effective, which in turn can improve the allocation of resources within the health care sector. Suppliers of health technology will have a higher motivation for innovation, as the investment in technologies which can be proven cost-effective will have a better chance of uptake when procurement is based on value rather than cost-minimization. The application of technology assessment is therefore crucial to ensure that investments are focused on those innovations that have a chance of being successful in the market. Finally, value-based health care in general, and value-based procurement in particular, yields more value for the patients, as more new technologies, proven effective, may be utilized in health care.

### 2.4 Research questions

The aim of the thesis was to apply a framework for early HTA, with the objective to guide the developers, at an early stage of product development, about the technology’s potential for being cost-effective and successful in the market. The thesis uses Ably Medical and the Ably Bed as a case and apply the framework of early HTA to investigate whether Ably Bed has a potential for being cost-effective. By following the early HTA framework and the suggestions for product
assessment, as presented by (IJzerman and Steuten, 2011), the following research questions emerged:

**Research question 1:**

*Is the Ably Bed in combination with common practice a cost-effective alternative to common practice only, for the prevention of HAPU?*

**Research question 2:**

*Is there an efficiency gap large enough for the Ably Bed to be a potentially cost-effective technology?*

**Research question 3:**

*What are the main drivers for technology uptake and factors for decision-making regarding procurement of medical devices?*

**Research question 4:**

*Which attributes should the Ably Bed have, to solve issues related to care and rehabilitation?*

The first two research questions are related to the cost-effectiveness of technology and will be answered by applying concepts from the theoretical framework, early HTA. Although the first two questions may be sufficient from a health economic perspective, they do not include the perspective of the users and the buyers of medical technology. If medical technology is treated differently than pharmaceuticals by decision-makers, regarding the assessment and procurement decisions, then estimating the cost-effectiveness will not be sufficient, as there are other factors affecting technology uptake. Consequently, the last research questions were included.
3 Theoretical framework

As value-based health care is about the efficiency of health care provision, health economics and economic evaluations are central to the concept of value. When it comes to health technology, the main theoretical framework is the assessment of technology, or HTA. The basics of HTA and economic evaluations will be introduced in this chapter. As the case of this thesis is involving a product which is still under development, the framework of HTA at an early stage will also be presented. This framework is built upon the concept of standard HTA but encompasses some methods and concepts that are considered as more suitable at the early development and pre-market stages.

3.1 HTA and economic evaluation

As resources are scarce, society should aim at achieving efficient allocation of resources. In health care, this implies that resources within the sector are allocated in such a way that we maximize health output. Hence, inefficiency exists when a reallocation of those resources would generate an increase in health output (Palmer and Torgerson, 1999). Allocative efficiency is based on the concept of opportunity cost of investment. For health care, this implies that the decision to invest in a technology can result in health forgone if the technology invested in, generates less health than the technology we chose not to invest in. For health technology, such as pharmaceuticals or medical devices, the opportunity cost is related to the incremental cost-effectiveness. More specifically, it is the cost related to the health benefits that the technology generates when compared to the next best alternative (Cosh et al., 2007). As there are opportunity costs related to every investment, and the budget for health care is finite, it is essential that decision-makers do good investment decision. HTA is a framework that is developed for this purpose exactly, namely to inform decisions in health care. HTA is defined by (WHO, 2014, p. 1) as:

«(…) the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. (…)»
There are two main processes in HTA; collection of data on evidence of the technology and the disease in question, and the analysis of this data through economic evaluation and decision-analytic modelling. The aim of decision-analytic modelling is to inform decision-makers about the potential cost-effectiveness of a particular technology, compared to the alternatives. The comparable alternative(s) of a new technology is the current gold standard technology, as only an increase in performance compared to this technology will be relevant in a reimbursement decision (Cosh et al., 2007). The reimbursement of health technology is based on the Diagnosis-Related Group (DRG) system. The DRG system include tariffs, through which the health care systems are funded, or reimbursed for their costs related to provision of care. In other words, it is an activity-based funding system, used partly or alone as a way of funding health care, both in Europe and North-America. For a medical technology to be reimbursed through this system, there must exist an appropriate DRG code in which the technology can be classified.

Economic evaluations can be a cost-minimization analysis, cost-benefit analysis, cost-effectiveness analysis (CEA) and cost-utility analysis (CUA), where the two latter are the most commonly used when assessing health care technology. Effects can be measured in terms of clinical (intermediate) outcomes such as cases averted, cholesterol level, or preferably final outcomes, such as life years gained and quality adjusted life years (QALY). In a CEA or CUA, the effect is normally measured in terms of QALYs. A QALY is a health outcome that captures effect, in the form of reduced morbidity and reduced mortality. Quality and quantity gains from treatment are incorporated into a single measure by multiplying HRQoL utility scores and the time spent in that health state. The HRQoL is the utility from being in a certain health state, measured on a scale from 0 to 1, where 0 reflects death and 1 perfect health. The HRQoL utility values can be measured by several types of instruments. The generic multi-attribute utility instrument, EQ-5D is among the most commonly used. By applying QALYs, a life year is adjusted to reflect the health state the patient is in, and the utility gained from being in that particular state. Thus, a year in a health state with a HRQoL utility of less than 1, generates less value than a year lived in perfect health, where utility equals 1.

Technologies are assessed and compared by estimating the incremental cost-effectiveness ratio (ICER), where the null hypothesis is that the mean cost-effectiveness of a particular health technology is unequal to the mean cost-effectiveness of a competing technology (Drummond and McGuire, 2001).
The ICER is calculated as Equation 1 above. The difference in costs between the technology being evaluated ($C_a$) and the alternative ($C_b$) is divided by the difference in effect between the technology ($E_a$) and the comparator ($E_b$). In other words, we divide the incremental costs on the incremental effects to get the ICER estimate.

$$ R = \frac{C_a - C_b}{E_a - E_b} = \frac{\Delta C}{\Delta E} $$  \hspace{1cm} (1)

Figure 1, shows a cost-effectiveness plane, with $\Delta C$ on y-axis and $\Delta E$ on x-axis. The figure illustrates whether the ICER represent a dominant (SE-quadrant), dominated (NW-quadrant) or trade-off (NE and SW quadrants) technology, compared to the alternative. An ICER placed in the north-east quadrant of the cost-effectiveness-plane represents a technology that is costlier, but also more effective than the comparing technology. Hence, a trade-off exists between costs and effects. An ICER in the north-west quadrant represents a technology that is dominated by the alternative. The south-east quadrant represents dominant ICERs, meaning the technology
in question is both less expensive and generates more effect than the comparator. This technology should therefore be implemented over the alternative. An ICER in the south-west quadrant represents a technology that is less costly, but also less effective compared to the alternative. The red stippled line represents the WTP for increased effect, or QALY gained, often referred to as the threshold ICER, denoted as \( \lambda \). Moreover, the threshold ICER represents the opportunity costs of investing in a certain technology, when technologies are mutually exclusive, and budgets are constraint. By definition, a technology or intervention is only cost-effective if the ICER is below the threshold (Drummond et al., 2015). Stating a WTP threshold have not been common practice in most countries. However, in the UK, The National Institute of Health and Care Excellence (NICE) have stated a threshold of 20,000 to 30,000 GBP per QALY (Chapman et al., 2014). This implies that any ICER falling above the WTP, will not be considered cost-effective, and consequently not be accepted.

The above theoretical concepts are the foundation of economic evaluation and decision-making concerning health technology. Full economic evaluations are usually carried out alongside or after a clinical trial, when data on the technology is available. The concepts are applicable also to early stage HTA. Although early HTA is based on the same theory, there are some differences and some other methods for determining cost-effectiveness and potential success of a product. The framework of early stage HTA will therefore now be presented in more detail.

### 3.2 Early HTA

Early HTA is, similarly to general HTA, a systematic evaluation of costs and effects of an intervention or technology. The difference of the two, is that early HTA can be applied as a tool for informing the supply side of technology, where the application of the methods can guide decisions concerning further development and investment. An argument for why medical technology companies should invest in early HTA, is that there is a need to inform decisions at an earlier stage of the product development (IJzerman et al., 2017). Regular HTA is performed when a product is given market access, and although it is a recognized framework for assessment of technology, it is based on information that the developer does not necessarily have at the early and critical stage of product development. Medical technologies have a different life-cycle compared to pharmaceuticals, and along with incremental innovations, performing full HTA is both costly and too time-consuming for technologies with such short life-time. Early HTA is therefore considered more suitable. Moreover, early HTA may impact
the design, and possibly increase the performance of the technology (IJzerman et al., 2017), which implies better effect and more patient value. Hartz and John (2008) define early HTA as economic evaluation performed to inform the developer about the technology’s future commercial viability. Early HTA is therefore a framework for decision-making on the supply-side of technology, rather than demand-side (Chapman et al., 2014). IJzerman et al. (2017, p. 731) defines early HTA as;

“All methods used to inform industry and other stakeholders about the potential value of new medical products in development, including methods to quantify and manage uncertainty.”

Economic evaluations are not always required for medical devices but may increase the likelihood of market authorization and market success, as it provides evidence of performance and cost-effectiveness. Figure 2 below gives a schematic overview over the decision-making process during product development, and the type of analysis that are suitable at the different stages. The chart is designed by Cosh et al. (2007), whom in their paper, describes an approach to decision making and economic evaluation at early stages, when a cost-effectiveness analysis will be highly speculative due to the surrounding uncertainty of the ICER. As we can see from the scheme, early economic HTA can be conducted after the idea of a new technology has been established, and research has been done on the patient population, epidemiology and the current treatments and technologies used. Headroom and return on investment analyses are used to determine potential for being cost-effective, and whether the technology will be favorable. An insufficiently large headroom that does not allow for incorporation of development and production costs in the product price, means that the product is unlikely to be cost-effective and the deterministic rule is to discard the technology. In order to make a more informed decision regarding the product and its development, early HTA, and full economic analysis will give information about the technology’s probability of being deemed cost-effective.
During product development and investment decisions, knowing whether a technology can be cost-effective or not, given optimal performance, may be just as relevant as knowing a technology’s potential level of cost-effectiveness. A way of approaching this issue, is to calculate the effectiveness gap between the standard technology being used today, and the new technology under development (McAteer et al., 2007). The Headroom method was first developed by Schulper and others (Girling et al., 2015), and is designed for this purpose exactly. The analysis determines the marginal value of the advantage of the new technology. Thereafter, one can calculate the incremental cost of the new technology, where it is still considered as
cost-effective. The analysis is called the Headroom method, as we calculate the commercial headroom for cost-effectiveness. It can be used as a method for setting a deterministic rule for further development (Girling et al., 2015). Additionally, the method can be used to determine the maximum reimbursable price (MRP) of a product, based on the WTP-threshold for additional effect. The price the developer can get for a technology will most likely not be equal to H (which is the MRP), but rather lie somewhere between H and U (Girling et al., 2012). Although the actual selling price most likely will be lower than the MRP, it is a good tool for developers of medical technology to estimate the potential commercial viability of a technology, at the very beginning of product development. Knowing the buyers WTP for additional QALY, allows the producer to set prices thereafter, hence ensuring maximum profits. A producer that does not know the added health benefit will not know the potential WTP for the value the product yields and risk underselling, or worse, rejecting potentially profitable innovations.

The method has proven to be a simple, yet rigorous framework for estimating whether a new technology will be cost-effective, without having performed a full economic evaluation (McAteer et al., 2007). The method is based on the same principles as economic evaluations of a medical technology, but as available data are limited at an early stage, it is a more simplified way of estimating the potential value of a technology (Girling et al., 2015).

For these reasons, the method has been gaining interest from the medical device industry. It is also noteworthy that the method do not only consider the surrounding uncertainty in an investment decision from the perspective of the developer and its investors, but also incorporates the expected additional value the technology may generate for the society as a whole (Markiewicz et al., 2016).

Equation 2 below, shows how the commercial Headroom estimate (H) is calculated. As H equals the MRP, this equation provides the maximal price developers could set on their product, according to the reimbursement agency’s WTP per gain in QALYs. Moreover, the headroom, H, corresponds to the net benefit for the health care provider given that the medical technology is provided free of charge. In other words, it is the headroom, or gap, for cost-effectiveness (Girling et al., 2015). The equation states that H is equal to the net reduction in health care costs (HCC) + \lambda * the additional QALYs that the product generates. Net reduction in health care costs (HCC) is calculated by estimating the incremental costs or savings of providing health care, by the use of the new technology, compared to the alternative, without including the
purchasing price of the technology. $\lambda$ represents the threshold ICER, which is the WTP for additional effect. The additional QALYs are the incremental QALYs generated when switching from the comparator to the new technology. The H estimate (the headroom) is thus corresponding to the ceiling cost of one unit, including both production and development costs, for which the technology could still be considered cost-effective (Girling et al., 2015).

$$ H = (\text{Net reduction in HCC}) + \lambda \times (\text{Additional QALYs}) $$

(2)

Although a technology under development has been evaluated as potentially being cost-effective, the developer and investors should gather more information before deciding on whether to invest in further product development. A factor in this decision is the potential return on investment, or the value of revenues net of production costs. The return on investment will depend on not only a product’s likelihood of being cost-effective, but also the potential market size. The return on investment is based on the headroom estimate (H), the estimated product costs and sales volumes (Girling et al., 2015). The return on investment can be calculated as Equation 3 below, where $V$ is the revenue, or the value net of production costs. $M$ is the projected number of products sold over a certain time horizon. $H$ is the headroom estimate, and $U$ is the expected cost of production per item.

$$ V = M \times (H - U) $$

(3)

The return on investment can also helpful in determining whether a product is worth continuing developing, based on whether revenues will cover the development costs. It is the future development costs that are of interest as sunken costs is here considered irrelevant.

### 3.2.2 Early economic evaluation

Economic evaluations are normally conducted alongside large, randomized clinical trials. During product development, and especially at the early stages, data from such trials are normally not available. Early economic evaluations and estimated cost-effectiveness of a product, where none or little data is available, is obviously extremely uncertain. However, they
may be important as some information is better than none, about the potential performance of the product. Early economic evaluation is based on the same principals and methods as standard economic evaluation. However, at an early stage, before full clinical trials are conducted, the evaluation is typically to a larger degree based on expert opinions, published literature and assumptions. Sensitivity analysis can be performed to assess the uncertainty surrounding the ICER. Although probabilistic sensitivity analysis may not be feasible at this stage, one- or two-way sensitivity analysis may be very informative as they provide information about which parameters affect the cost-effectiveness of the technology the most. Thus, giving indications to the developers as to where they should focus their work in order to enhance the probabilities of the product being proven cost-effective at a later stage.

3.2.3 Stakeholder Preference

A new product or technology’s success when entering the market, will to a large degree depend on its acceptance by the user, which for medical devices are the health care personnel or in some cases, the patients. Involving (multiple) stakeholders during product development may improve the success of a new technology, as it can have impacts on i.e. the performance and usability, and hence the user experience and acceptance of the technology (Martín et al., 2016). A stakeholder can be defined as (Britannica Academic, 2018 p. 1)

“any individual, social group or actor who possesses an interest, a legal obligation, or other concern in the decisions or outcomes of an organization, typically a business firm, corporation, or government. Stakeholders either affect or are affected by the achievement of an organization’s objectives.”
Although medical devices can be reach the end consumers, patients and professionals either directly or via a health organization, regulatory bodies and the financers of health care are important stakeholders as they enable the flow of medical devices in the industry.

As Figure 3 illustrates, there are multiple types of stakeholders in the medical technology industry, both regulatory bodies and policy makers, health care professionals, decision-makers of the procurement of technology, providers of health care and of course the patients. The engagement of stakeholders should involve multiple stakeholders of different types, to gain a broader perspective and knowledge from multiple areas relevant to both the development and the success when a product enters the market. As medical devices need to be approved and granted market authorization before it can enter the market, regulatory bodies such as the Food and Drug Administration in the US, NICE in the UK or the International Organization of Standardization (ISO Standards), are key stakeholders for the success of the technology. Medical professionals and the procurement division of medical equipment at health care institutions are also key stakeholders, as the decision on whether to invest in one technology over another may largely be affected by their preferences.

There are several methods for assessing stakeholder preferences and need for technology within health, as well as their potential value (IJzerman et al., 2017). Among them are choice models, multicriteria decision-analysis, systematic literature review and in-depth interviews. The first
is a method where relevant stakeholders preferences for new technologies are elicited. Belief elicitation is one way of analyzing stakeholder preferences, which can be useful in determining potential use of a medical devices. The second method can be used to estimate the technology’s value at different points in time during development, and inform decisions concerning allocation of resources between the development of different types of products. Literature reviews could reveal preferences through investigating what technologies have reached uptake in the past, and the attributes they have. In-depth interviews with stakeholders can reveal needs and preferences for the technology through open ended questions on relevant topics.
4 Methodology

The research in this thesis is based on three different analyses, utilizing both quantitative and qualitative research methods. An early stage economic evaluation was performed to estimate the potential cost-effectiveness of the Ably Bed. Moreover, a Headroom analysis was conducted, based on the economic evaluation, to further assess the potential for cost-effectiveness of the technology. These two analyses form the primary research of the thesis. Finally, interviews with key stakeholders was performed as a secondary data source and functioned as a supporting analysis to the technology assessment. The three analyses are based on the theoretical framework for early HTA. They are complementing each other, ensuring a more complete assessment. Only the potential effect on pressure ulcers has been considered in the analysis, potential effect on patient falls and nurse load was excluded. All three analyses are presented in more detail in the following sub-chapters.

4.1 Early economic evaluation

The objective of this analysis was to gain information on whether the Ably Bed has potential for being a cost-effective technology. The analysis performed was a cost utility analysis, where the cost-effectiveness of the Ably Bed in combination with common practice of prevention of HAPUs is expressed in terms of incremental cost per QALY gained (ICER).

4.1.1 Intervention and comparator

The intervention assessed, is the Ably Bed in combination with common practice for prevention of HAPUs. In order to be able to say something about the interventions’ cost-effectiveness, it was compared to the common practice for prevention of pressure ulcers. The common practice of PUs at hospitals may vary between countries, hospitals and wards. However, it normally includes risk assessment by the use of the Braden scale, use of pressure relieving overlays and mattresses, including high specification and pressure alternating mattresses, regular skin assessment, turning of patient, skin care, wound dressings, nutritional supplements and ointments (Padula et al., 2011, Schuurman et al., 2009).

The Ably Bed is not designed to replace common practice for prevention. Rather, it is meant to function as a supplemental technology for reducing the risk of developing PU. The Ably Bed
was therefore considered as an *add-on* technology, where the special mattresses could be used in combination with the bed. The Ably Bed in combination with common practice was the assessed prevention method. Common practice for prevention was the comparator.

### 4.1.2 Perspective

As the economic evaluation was performed with the objective to inform the developers and investors about the potential cost-effectiveness of the Ably Bed, the perspective chosen was the perspective of the buyers, more specifically, health care providers.

### 4.1.3 Population

The target population of the study was patients admitted to a hospital, receiving preventive measures for pressure ulcers. The practice for prevention may vary between hospitals. According to Schuurman et al. (2009) preventions should be given to all patients admitted for 5 days or more as those are at risk of developing HAPUs. However, preventive measure may be given to all patients at inpatient wards.

### 4.1.4 Time horizon

The healing time for PU was derived from the literature. According to Bennett et al. (2004), mean healing time per PU grade is 28.4 days for grade I, 93.8 days for grade II, 127.4 days for grade III and 154.7 days for grade IV. No healing time exceeding a year was found. The time-horizon for this analysis was therefore set to 1 year.

### 4.1.5 Model structure

To assess the cost-utility of the intervention, decision modelling was performed, and a probabilistic decision-tree model was developed using Microsoft Excel. Decision-trees are widely used in economic evaluations but are often considered simple model structures with certain limitations. However, decision-trees may be preferred due to its simplicity, and as this was an early-stage economic evaluation, it was considered to be a suitable choice of model, especially in a setting where it may be used by non-experts, such as in an entrepreneurial medical device company.
In this model, the patient entered the decision-tree model when admitted to the hospital. The structure of the model was designed with the intention to simplify a hospitalization of a patient receiving preventive HAPU care. After a patient received either of the two preventive strategies, patients could either develop a HAPU or not. When a HAPU developed, it could either heal normally, relapse after treatment, or develop into a HAPU of grade III/IV. A patient that developed HAPU of grade III/IV could either be healed, experience a relapse of same grade, complications or die. Complication and death was included here to reflect that patients with HAPUs of this stage are normally older, very sick and bed bound patients, with a generally higher chance of both complications and death (Bredesen et al., 2015, Coleman et al., 2013). Figure 4 demonstrates the structure of the decision-tree.

Figure 4 Decision-tree.

Square-shaped nodes represents a decision. Circular nodes are chance-nodes with conditional probabilities for each arm. The triangular nodes are end-nodes representing final outcomes.
The square-shaped decision node in the decision tree indicates the decision point between the two alternatives, Ably Bed in combination with common practice for prevention or common practice only. The circle-shaped chance nodes indicate where alternative outcomes were possible. There are conditional probabilities connected to each point marked with a circle-shaped node. This implies that the probabilities sum up to one, and that the events coming from the same chance node are mutually exclusive. The triangular-shaped terminal nodes at the end of each branch indicates end-points for each possible path of the model. The path-probabilities are unconditional probabilities. The total expected effect of each decision (intervention and comparator) was calculated by summing all the probabilities for each patient pathway belonging to each decision and multiplying it with the utility value for each specific outcome. Total expected cost for intervention and comparator was found by multiplying pathway probabilities belonging to each decision with the total cost related to each pathway.

4.1.6 Model inputs

The inputs in the cost-utility model was derived from several different sources. Model parameters for both probabilities, HRQoL utilities and costs, were found in literature by performing literature searches. The searches were done from Oria and PubMed, using key search words such as: “prevention pressure ulcer”, “cost of pressure ulcer”, “hospital acquired pressure ulcer”, “cost-effectiveness pressure ulcer”, “HRQoL pressure ulcer” and “pressure ulcer prevention”. Other model inputs were expert opinions, derived from the stakeholder interviews. Some inputs were estimates coming directly from the developer, Ably Medical AS.

Health outcome:

The primary health outcome of the analysis was QALYs, which incorporated both the length of life and the utility values for a specific health state; HRQoL. The end-point utilities connected to each path-way in the decision tree are shown in Table 2.

QALYs were calculated by multiplying the HRQoL utility values with the time spent in the health state. As the time-horizon of the study was one year only, the QALYs were equal to the HRQoL utility values. The ICER was estimated using the utility scores for the five possible end points in the decision tree, which were; No HAPU, HAPU stage I/II, HAPU stage III/IV, HAPU stage III/IV with complication, and dead. Utility values used in the analysis were taken from Padula et al. (2011), who performed a CEA comparing the cost-effectiveness of standard-care
and prevention of HAPUs. As no utility score of having a PU stage III/IV with complications was found in the literature, it was for modelling purposes assumed to be 15% lower than the utility of having a PU grade III/IV with no complication.

<table>
<thead>
<tr>
<th>Input parameter</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility of being PU free</td>
<td>1.00</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Utility of having HAPU stage I/II</td>
<td>0.78</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Utility of having HAPU stage III/IV</td>
<td>0.60</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Utility of having HAPU stage III/IV with complication</td>
<td>0.51</td>
<td>Assumed</td>
</tr>
<tr>
<td>Utility of being dead</td>
<td>0.00</td>
<td>Padula et al. 2011</td>
</tr>
</tbody>
</table>

Values are ranging from 0-1, where 1 represents utility of having perfect health and 0 represents utility of being dead.

**Costs:**

As the evaluation was done from a health care perspective, only costs that were assumed to fall on the health care provider, in this case the hospital, was included. The model did not incorporate costs that were not directly related to the prevention and treatment of HAPU. Hence, the total costs related to each of the arms (patient pathways) in the decision-tree, did not include costs of care for the treatment that the patient is hospitalized for, as well as “hotel” costs per day and other administrative costs. Table 3 gives an overview over all the different costs inputs in the model. Costs where converted to NOKs by following the Norwegian National Banks yearly exchange rates (Norges Bank, 2018). The numbers where thereafter adjusted for consumer price index to reflect inflation. Inflation rates was calculated based on Statistics Norway (2018) index overview. Complete cost calculations are available in Appendix.

The cost of common practice was taken from the Dutch study by Schuurman et al. (2009). In their micro-cost study, 180 cost items related to common practice were identified and grouped into the categories; cost for repositioning, cost for mobilization, cost for wound care and cost for resources such as special beds, mattresses, wound dressings, nutritional supplements and
ointments. The cost of treatment of HAPU stage I/II and III/IV were derived from the same study. The main cost items for treatment were similar to the prevention (special mattress, repositioning, mobilization, ointment, wound care and wound care products), and increased by the grade of PU as the time to heal increased. As the 4 grades are grouped into group I/II and III/IV, costs were based on the average of the two, in order to find cost per group. For simplicity, cost of relapse were set to be equal the treatment for each of the two severity groups.

The cost of Ably Bed per patient was calculated based on a unit price of USD 25 000 (NOK 206 575) with an exchange rate of 6.3696. It was assumed that the bed had a life time of 10 years, resulting in a yearly cost of USD 2500 (NOK 20 658). The unit price of the bed per patient, with an average LOS of 4.2 days (Statistics Norway, 2017), was then calculated to be USD 29 (NOK 237). Calculations can be found in Appendix.

Cost of complication was based on the Danish study by Mathiesen et al. (2013). In their study, critical colonization, cellulitis and osteomyelitis was included as possible complications. The total cost of complication was calculated as the average of these three complications in order to get a cost that would suite the structure of the model, where complications were grouped into one arm in the decision-tree. Calculations can be found in Appendix.

<table>
<thead>
<tr>
<th>Table 3. Cost parameters.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input parameter</td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>Cost of Ably Bed per patient</td>
</tr>
<tr>
<td>Total cost of treatment PU stage I/II</td>
</tr>
<tr>
<td>Total cost of treatment PU stage III/IV</td>
</tr>
<tr>
<td>Cost of death</td>
</tr>
<tr>
<td>Cost of relapse HAPU stage I/II</td>
</tr>
<tr>
<td>Cost of relapse HAPU stage III/IV</td>
</tr>
<tr>
<td>Cost of complication</td>
</tr>
</tbody>
</table>

Parameters are used in the model by assigning costs to each of the arms in the decision-tree. Full calculations are available in Appendix.


Probabilities:

The conditional probabilities in the decision tree are presented in Table 4. The incidence rate, or probability of developing a HAPU was based on an expert opinion retrieved from stakeholder interviews.

Table 4. Probability parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When prevention is given:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prob. of HAPU I/II</td>
<td>0.130</td>
<td>Expert opinion</td>
</tr>
<tr>
<td><strong>When HAPU I/II have developed:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prob. of being healed from HAPU I/II after treatment</td>
<td>0.652</td>
<td>Calculated</td>
</tr>
<tr>
<td>Prob. of experiencing a relapse of HAPU I/II after treatment</td>
<td>0.116</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Prob. of developing HAPU III/IV</td>
<td>0.233</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td><strong>After a relapse:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prob. of being healed after 2nd round of treatment</td>
<td>0.990</td>
<td>Assumed</td>
</tr>
<tr>
<td><strong>When HAPU III/IV is developed:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prob. of being healed from HAPU III/IV after treatment</td>
<td>0.698</td>
<td>Calculated from Padula et al. 2011</td>
</tr>
<tr>
<td>Prob. of experiencing a relapse of HAPU III/IV after treatment</td>
<td>0.035</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Prob. of complication when having HAPU III/IV</td>
<td>0.195</td>
<td>Mathiesen et al. 2013</td>
</tr>
<tr>
<td>Prob. of death when having HAPU III/IV</td>
<td>0.072</td>
<td>Padula et al. 2011</td>
</tr>
<tr>
<td>Prob. of being healed from HAPU III/IV when placed in an Ably Bed*</td>
<td>0.675</td>
<td>Assumed</td>
</tr>
<tr>
<td><strong>Relative risk reduction with Ably Bed:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative risk reduction of HAPU I/II</td>
<td>0.900</td>
<td>Assumed</td>
</tr>
<tr>
<td>Relative risk reduction of HAPU III/IV</td>
<td>0.900</td>
<td>Assumed</td>
</tr>
</tbody>
</table>

Values are representing conditional probabilities that were used in the decision tree. Values are split up according to the structure of the decision tree to illustrate probabilities that are conditional on each other.

* Due to the relative risk reduction of HAPU III/IV from the Ably Bed, the value was adjusted to ensure that conditional probabilities summed up to 1.
4.1.7 Key model assumptions

To be able to assess the cost-effectiveness of a technology still under development, on which no clinical testing has been done, assumptions had to be made in order to be able to draw conclusions. The following paragraphs describes the assumptions in the model.

It was assumed that all patients admitted to a hospital were given preventive measures for HAPU. Hence, no specific patient population other than being admitted to a hospital, was targeted. It was also assumed that patients were PU free at admission and had an equal probability of developing a HAPU.

In order to simplify the model, the condition that the patient was hospitalized for, was not considered. Thus, a patient that does not develop a HAPU, was assumed to be perfectly healthy at discharge, with a HRQoL utility value of 1. The HRQoL when having a HAPU stage III/IV with complication was assumed to be 15% lower than when having a HAPU stage III/IV without a complication.

Treatment of PU was assumed to not exceed a year, and patients were assumed to stay hospitalized during the whole treatment time.

Probabilities in a decision tree are conditional, and some probabilities therefore had to be calculated based on the probabilities found in the literature that were connected to the same chance-node. The probability of being healed from the HAPU, at both stage I/II and III/IV was assumed to be 1 after a second round of treatment. The values for relative risk reduction of HAPU for both stage I/II and III/IV was based on estimates (target goals) of Ably Medical AS.

The main cost groups in the model were the cost of common practice for prevention of HAPU, cost of the assessed technology and cost of treatment. The model assumes no costs other than CP or CP + Ably Bed if the patient does not develop a HAPU. To be able to calculate the cost of a patient bed per hospitalization, several assumptions had to be made. First of all, a patient bed was assumed to have a life time of 10 years. Moreover, a patient was assumed to stay hospitalized 4.2 days on average (Statistics Norway, 2017). Furthermore, it was assumed full use of the bed. A cost of a relapse is assumed to be equal to the first round with treatment of that same grade of PU, implying same need of resources and same costs for the second round.
4.1.8 Sensitivity analysis

Sensitivity analyses can be used to assess how uncertain the result is, or how sensitive the ICER is to changes in the input parameters. By performing these types of analyses, one can test the models’ validity, and thus make better informed decisions (Drummond et al., 2015). Both deterministic, one- and two-way sensitivity analysis as well as a probabilistic sensitivity analysis was performed. The outcome was considered to be sensitive when it changed the decision. In other words, when the ICER was no longer to be consider as acceptable.

Deterministic sensitivity analysis:

Deterministic, one- and two-way sensitivity analysis was performed on several of the input parameters. One- way (univariate) sensitivity analysis gives information about the model sensitivity to changes in one specific input parameter. The result was considered as robust when the ICER did not go above the threshold ICER. This was defined as ICERs above a WTP threshold of NOK 200 000. One parameter is changed, within a range of plausible values, holding all other input variables constant. The analysis provides the different model outputs corresponding to each value the input variable takes. The parameter range can be taken from confidence intervals calculated based on e.g. randomized controlled trials. As no data is available on the technology itself, and few of the studies used in the analysis reported confidence intervals for the values, the chosen ranges for each parameter tested was set to +/- 50%, with the exemption of the parameter for utility of being PU free and the parameters for relative risk reduction. The utility of being PU free was assumed to be close to 1 and was therefore only reduced by 50%. The relative risk reduction parameters were increased by 10%, up to 0.99, and reduced by 50%. The parameter for price of the Ably Bed per patient was varied up to a 500% increase from the base value. This was done because the parameter was considered to be extremely uncertain. The price of the bed per patient did not only depend on the unit sales price but also the average LOS and the degree of utilization. The model was also tested for sensitivity to parameter changes by varying two-variables at a time, also called a two-way sensitivity analysis (multivariate). The analysis is based on the same principle as one-way sensitivity, however, a tow-way or multivariate analysis may give a more realistic view on how the output may change according to the input variables, as some input variables are likely to change simultaneously. Table 5 gives an overview over the parameters tested, their base case value and the ranges of plausible values the parameters could take.
Table 5. Parameter ranges.
Table is showing the parameters the one- and two-way sensitivity analysis was performed on.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Base case value</th>
<th>Range</th>
<th>Change from base case value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prob. of HAPU stage I/II</td>
<td>0.13</td>
<td>0.065 - 0.195</td>
<td>+/- 50%</td>
</tr>
<tr>
<td>Relative risk reduction</td>
<td>0.900</td>
<td>0.450 – 0.990</td>
<td>+ 50%, -10%</td>
</tr>
<tr>
<td>HAPU stage I/II**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative risk reduction</td>
<td>0.900</td>
<td>0.450 - 0.990</td>
<td>+ 50%, -10%</td>
</tr>
<tr>
<td>HAPU stage III/IV**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability of complication</td>
<td>0.195</td>
<td>0.098 - 0.300</td>
<td>+/- 50%</td>
</tr>
</tbody>
</table>

HRQoL Utility values:

| Utility of PU free* | 1.00 | 0.500 - 1.000 | -50% |
| Utility of complication | 0.51 | 0.255 - 0.765 | +/- 50% |

Costs:

| Cost of common practice for prevention | NOK 3 163 | NOK 1 582 - NOK 4 745 | +/- 50% |
| Cost of Ably Bed per patient | NOK 237 | NOK 119 - NOK 1 422 | - 50% + 500% |
| Total cost of treatment of a PU stage I/II | NOK 4 198 | NOK 2 099 - NOK 6 297 | +/- 50% |
| Total cost of treatment of a PU stage III/IV | NOK 14 556 | NOK 7 278 - NOK 21 834 | +/- 50% |
| Cost of complication | NOK 37 096 | NOK 1 8548 – NOK 5 5644 | +/- 50% |

* Utility are values on a range from 0-1. The parameter was therefore only decreased by 50%.
** Parameters are multiplied with the parameters for probability of HAPU stage I/II and III/IV. The smaller the value, the larger the relative risk reduction and vice versa. Relative risk reduction is increased to 55% and reduced to 1%.

** Probabilistic sensitivity analysis:**

A probabilistic sensitivity analysis (PSA) was performed to quantify the uncertainty, and thereby be able to assess the probability of making the wrong decision. To perform a PSA all parameters were assigned distributions from were random numbers could be drawn. 2000 Monte Carlo simulations where performed where random numbers from each assigned
distribution, for each parameter, was drawn and where the output was calculated for every simulation. Utility parameters were assigned beta distributions to ensure only numbers between 0 and 1 could be draw. Probabilities were either assigned beta or Dirichlet distributions. Dirichlet distributions was assigned to those parameters where more than two were conditioned on each other, to ensure that the probabilities drawn in the simulation did not sum up to more than 1. Cost parameters were assigned gamma distributions to ensure that only positive numbers could be drawn. None of the sources of the parameters found in the literature provided information about standard errors. The standard errors were estimated by multiplying the parameter values by 20%, following the method described by (Briggs et al., 2006). Although this less precise than standard calculations of SE, it was considered a good option in this case. For some parameters, like the probability of being healed after a second round with treatment, where the model assumes that the probability is 1 or 0.99, the standard error is estimated by multiplying the parameter with 5%. The same is done for the utility of being healthy (PU free) and the utility of being dead, which is 1 or 0.99 and 0 or 0.001 respectively, as the variation in utility can be assumed to be small for this parameter. The simulated ICERs from the PSA was presented as a scatterplot in a CE-plane.

**Cost-effectiveness acceptability curve:**

The uncertainty was further addressed by presenting the probability that the Common Practice + Ably Bed was cost-effective for several different WTP thresholds, \( \lambda \). An ICER was acceptable if it fell below the threshold ICER. The probability the strategies would be considered as cost-effective was calculated for a set of different WTP thresholds. For each of the 2000 Monte Carlo simulations, the net monetary benefit (NMB) was calculated by the formula in Equation 4 below. The intervention with the highest NMB for each simulation was identified and the probability for each of the interventions being cost-effective for the different thresholds was thus equal to the proportion of the 2000 simulations where each had the highest NMB (Barton et al., 2008).

\[
NMB = \lambda \cdot \mathbb{E} - C
\]  
(4)

The cost-effectiveness curve (CEAC), was then plotted for both Common Practice + Ably Bed and Common Practice only, where the probability for each of the interventions being cost-effective was presented.
4.2 Headroom Analysis

The analysis of the commercial headroom available was conducted by applying the methods presented by Girling et al. (2015). In their article they present the Headroom approach to device development for suppliers of medical devices. Headroom calculations can be done at several time points of product development but should optimally be conducted the first time at a very early stage of product development, prior to investing in more advanced economic evaluations. As Ably Medical already have been working on their technology for several years, and an economic model was built as part of this research, the Headroom analysis was in this case based upon the model of the CUA. For this reason, the Headroom analysis is presented as the second method for assessment of the technology.

In the analysis, two different calculations were performed, Headroom estimate H, and the value V, net of production costs. To conduct the analysis, certain assumptions had to be made. The unit cost of production, estimated by Ably Medical AS, was set at USD 12 000 (≈ NOK 97 000) the first years of production, and USD 6 000 (≈ NOK 49 000) when full production is reached. The number of beds to be sold each year was estimated by Ably Medical AS to be 500 in year 2019, 2 600 in year 2020, 8 000 in year 2021, 12 000 in year 2022, reaching a stable sales quantity of 25 000 beds annually from year 2025. The analysis was performed under different scenarios. Firstly, the calculations were done with two different WTP thresholds of NOK 200 000 and NOK 300 000. Secondly, calculations were based on two different assumptions on average length of stay (LOS). In order to find the total net benefit for each patient bed, the expected life time of the bed and the average number of patients in one bed per year, had to be included in the analysis. According to Statistics Norway (2017), the average LOS at a hospital is 4.2 days, across all departments and patient groups. However, patients with PUs are expected to have a prolonged LOS (Bredesen et al., 2015, Bennett et al., 2004), as they often are admitted with more severe diseases, and due to the prolonged treatment period when HAPUs develop. To demonstrate this, additional calculations of the commercial headroom for costs were performed, with an average LOS of 15 days.

The headroom estimate H, was calculated as Equation 2 in Chapter 3. The net reduction in HCC was calculated by applying the decision tree model in the CUA, leaving out the price of the Ably Bed. The additional QALYs gained by the technology of the Ably Bed was also extracted from the CUA. The value of sales net of production costs, V, were calculated by applying Equation 3, also presented in Chapter 3.
4.3 Stakeholder interviews

The stakeholder interviews were conducted to gather secondary data which would support the quantitative analyses of the technology assessment. The respondents were also asked to comment on the model, input parameters used in the model and the structure of the decision tree. Although this part of the interview was not analyzed, it contributed to the economic evaluation, by allowing for a preliminary validation of the model, the respondents comments were also taken into consideration when developing the model.

The stakeholder analysis was carried out as explorative, semi-structured interviews. Three main topics were discussed, (value-based) procurement of medical technologies, HAPUs and the technology of the Ably Bed. Questions were formulated as open-ended. Sub/ follow-up questions were also formulated in order to ensure that additional information could be extracted. Two different interview guides were developed, to ensure that more relevant questions were asked to the different groups of stakeholders. Both are available in Appendix (in Norwegian). Interview guides are not meant to be a structured protocol, but rather a list of topics to be covered (Taylor et al., 2016). The interview guides were therefore not strictly followed. All interviews were recorded and transcribed in order to gather as much information as possible. Respondents were informed and agreed on this before the interview started.

To ensure a broad perspective of the analysis, respondents representing different types of stakeholders were selected. Health care personnel, management within procurement and innovation, as well as regulatory agencies, were considered as the most relevant stakeholders concerning decision of market access and success for the Ably Bed. The sampling of key interview informants was done by using purposive sampling, meaning that the interview respondents were chosen based on their field of work, position, and willingness to participate. In total 6 stakeholders were asked to participate, but only three were willing to, and had the time to participate. As this was not a stand-alone analysis, but rather a part of a total technology assessment, a small sample size was considered as sufficient. An overview over the respondents is presented in Table 6.
4.3.1 Analysis

Qualitative data can be analyzed in a number of different ways, and the chosen method for the analysis should depend on the type of information the researcher needs (Walliman, 2006). The interviews were conducted for explorative rather than comparable purposes. The method used for analyzing the interviews was based on the approach; qualitative interviewing and thematic, direct content analysis (Taylor et al., 2016). The aim of this type of analysis is to validate or extend a theory by asking questions based on it. Categories can be predetermined and based on the theory. The analysis of the data started by transcribing the interviews following an edited transcription method, where parts of the audio file, such as “uhms” and “chaugs” was left out, and where some sentences was restructured to make sense in a written language. The transcripts where then closely read through and notes were made about the first impressions. The relevant phrases, sentences and words in each interview was categorized according to the predetermined topics and codes. Content that was considered as relevant but did not directly fit the predetermined codes, were categorized separately and labelled.
Table 7. Topics and codes used in analysis

Topics were decided prior to conducting the interviews, codes were either predetermined or developed during analysis as new relevant information emerged.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Codes</th>
<th>Time of code development</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Value based) procurement of medical technology</td>
<td>User needs</td>
<td>During analysis</td>
</tr>
<tr>
<td></td>
<td>Competition</td>
<td>During analysis</td>
</tr>
<tr>
<td></td>
<td>Decisive factors</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Innovative procurement</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Value-based procurement</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Implementation</td>
<td>During analysis</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>Prevention</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Processes</td>
<td>Predetermined</td>
</tr>
<tr>
<td>Ably Bed</td>
<td>Requirements (need to have)</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Preferences (nice to have)</td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Opinions about technology</td>
<td>During analysis</td>
</tr>
</tbody>
</table>

4.3.2 Ethics

The respondents were asked to sign a contract of informed consent. A copy of the contract is available in appendix. The respondents were informed that they had the right to withdraw for any reason, at any time and that the interview would be recorded for later transcribing. Moreover, the respondents were deidentified. The topics discussed in the interviews were regarded as not having any negative impact on the respondents.
5 Results

As the research is based on three different analyses, this chapter is split into three sub-chapters, where the results from each is presented, starting with the CUA, followed by the Headroom analysis and ending with a presentation of the results from the stakeholder interviews. The research question relating to each analysis is answered in the first paragraph for each of the analyses.

5.1 Cost-utility-analysis

Based on the deterministic CUA alone, Ably Bed in combination with common practice is a cost-effective alternative to common practice only, for the prevention of HAPU. However, the result did not prove robust to changes in all the input parameters, and the probabilistic sensitivity analysis shows that the strategy, common practice only, is the preferred strategy, with a 10 percentage points larger probability of being cost-effective.

5.1.1 Deterministic cost-utility analysis

The results from the deterministic CUA is presented in Table 8. The cost-effectiveness results indicate that Ably Bed in combination with common practice for prevention of HAPU, is in fact cost-effective. The strategy yields higher costs per admission but generates more effect, in the form of QALYs, compared to common practice alone. The total cost of the common practice per admission is expected to be NOK 4 472, compared to NOK 4 515 when the Ably Bed is added to the prevention and treatment strategy, resulting in an increase in expected costs of NOK 43. The Ably Bed in combination with common practice has an expected effect of 0.001 additional QALYs compared to common practice alone. As the time-horizon of the analysis is one year, the increase in utility equals the QALY generated. Evidently, the deterministic analysis yields a result where Common Practice + Ably Bed is a cost-effective strategy over common practice only, given that the WTP threshold is above NOK 41 215.
Table 8. Result, deterministic CUA

The table is showing the result from the CUA. Incremental QALYs and costs are calculated as you move from the strategy common practice to Common practice + Ably Bed.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Total costs</th>
<th>Total QALYs</th>
<th>Incremental cost (ΔCost)</th>
<th>Incremental effect (ΔQALY)</th>
<th>ICER (ΔCost / ΔQALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Practice</td>
<td>NOK 4 472</td>
<td>0.984</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Practice + Ably Bed</td>
<td>NOK 4 515</td>
<td>0.985</td>
<td>NOK 43</td>
<td>0.001</td>
<td>NOK 41 215</td>
</tr>
</tbody>
</table>

5.1.2 Sensitivity analysis

Deterministic sensitivity analysis

The results from the one-way sensitivity analysis on model sensitivity to changes in parameters is presented in a tornado diagram in Figure 5. The one-way sensitivity analysis shows that the ICER is robust to changes for several of the parameters, although some parameters have a substantially larger impact on the cost-effectiveness than others. A few parameters may also have a large enough impact to change the decision, as the ICER is above a WTP threshold of NOK 200 000.

![Figure 5 Tornado diagram, model sensitivity to changes in parameters.](image)
The parameters are varied by +/-50% for most variables. +/- 10% is included to illustrate the model sensitivity to a smaller change. For relative risk reductions, the values have been turned in order for the figure to illustrate the result from changing the relative risk reduction, as a smaller input parameter implies a larger relative risk reduction. Values are ICERs and all values are in NOKs.

The model is indeed sensitive to changes in the parameter of the risk of developing a HAPU of grade I/II. There is a negative correlation between the parameter and the ICER, as a decrease in the parameter, increases the ICER. With a probability of developing a HAPU of 6.5%, the ICER increases by 552% up to NOK 268 862,32. For a WTP threshold of NOK 200 000, Common Practice + Ably Bed is in with this ICER, not a cost-effective strategy. However, as the parameter increases, the ICER declines and the cost-effectiveness level is improved. The parameters impact on the model result is also presented in Figure 6.

![Model sensitivity to changes in probability of developing HAPU I/II.](image)

*The figure is illustrating the relationship between the probability of developing a HAPU of stage I/II when admitted to hospital and the ICER. The blue graph is the ICER and the red is the threshold ICER, or WTP per QALY.*

A relative risk reduction of 1% (parameter=0.99) for HAPU stage I/II from the Ably Bed, is associated with a decrease in the cost-effectiveness level by 534.6%, to and ICER of NOK 261 58. When relative risk reduction is at 55% (parameter=0.45), the ICER is – NOK 156 121. The model is less sensitive to changes in the relative risk reduction on HAPU grade III/IV. A
relative risk reduction of only 1% yields an ICER of NOK 165 279, and the result remains intact. A 55% increase in relative risk reduction yields an ICER of - NOK 74 755.

The utility of being free from HAPU, assumed here as being perfectly healthy with a HRQoL of 0.99 (close to 1), have a large impact on the ICER. When the utility of being free from HAPUs is reduced by half, the ICER increases to NOK 246 102, which is 497% higher than the base case ICER, and not acceptable with a WTP threshold of NOK 200 000.

The ICER is negatively correlated to the price of treatment of both severity groups of HAPU. The ICER changes by 97.4% in each direction as the cost of treatment of HAPU III/IV is varied by 50% from the base case value. The treatment cost of HAPU stage I/II has less impact on the ICER, with a variation by 63.5% in each direction.

The result from the one-way sensitivity analysis on the parameters for complication, probability, utility and cost, showed that the model is not particularly sensitive to these parameters. A 50% reduction in the risk of complication when having a HAPU of stage III/IV is associated with a decrease in the cost-effectiveness by 38% to an ICER of NOK 56 885. A 50% increase in the risk, generates an ICER of NOK 13 783, equal to a 66.5% reduction from the base case. The ICER is positively correlated to the HRQoL utility value of having a HAPU of stage III/IV and complication. A 50% reduction in the utility value reduces the ICER by 21.3%, whereas a 50% higher parameter value, generates an ICER that is 38.3% higher than the base case. The model is more sensitive to the parameter for cost of complication. A change in the base case value of +/-50%, is associated with a 48.4% change in the ICER in each direction, where a reduced price generates a lower cost-effectiveness and vice-versa. The ICER does not increase to unfavorable levels, and the decision therefore remains intact.

The result of the one-way sensitivity analysis on the cost of common prevention indicates that the model is close to insensitive to changes in the price of common practice for prevention.

Figure 7 presents the results from the one-way sensitivity analysis performed on the parameter for the price of Ably Bed per patient. As one can read form the figure, the model is sensitive to changes in the price of the Ably Bed. An increase in the price per patient is associated with an increase in the ICER, thus a decline in the cost-effectiveness level. The ICER is -NOK 72 588 when the unit price decreases by 50% from the base value of NOK 237 per patient. A 100% increase in the price generates an ICER of NOK 268 822. A 500% increase in the price of the
bed, results in a very high ICER of NOK 1 179 247, assuming that the WTP threshold is NOK 200 000 only. The price of the bed per patient can increase up to 60-70% from the base case value. At a 60% increase in the value, the price is NOK 379 and the corresponding ICER NOK 177 779. At a 70% increase in the value, the price is NOK 403, and the corresponding ICER NOK 200 540, just above the WTP threshold of NOK 200 000.

Figure 7 Model sensitivity to changes in price of Ably Bed per patient.

The blue graph is the ICER and the red is the threshold ICER, or the WTP per QALY

Figure 8 presents the results from the two-way sensitivity analysis on relative risk reduction on HAPU stage I/II and the price per patient of the Ably Bed. The green shaded area represents ICER that are smaller than the base case ICER of NOK 41 215. ICERs in the yellow area are larger than the base case, but still below the potential WTP threshold of NOK 200 000. The red area is representing ICERs that are above this threshold. As the price is reduced and the relative risk reduction increases, the ICER becomes increasingly favorable.
Figure 8 Two-way sensitivity on relative risk reduction of the Ably Bed, on HAPU on I/II and the price of the Ably Bed per patient.

Row values are input parameters for the relative risk reduction of HAPU I/II and the % incline / decline from base case relative risk reduction. Column values are the cost of ably bed per patient and the % increase/ decrease from base case. Values in shaded area are ICERs. Red area represent ICER above a WTP threshold of NOK 200 000, yellow area are ICERs above the base case ICER of NOK 41 215, and green area are ICER below NOK 41 215.

Figure 9 presents the result from the two-way sensitivity analysis on the relative risk reduction from the Ably Bed on both severity groups of HAPU. The ICER is negatively correlated with the relative risk reduction, as a higher relative risk reduction generates lower ICER values. When both parameters for the relative risk is reduced by 50% from the base case values, the ICER decreases to -NOK 149 600, an increase in cost-effectiveness by 462.9%. As the parameters are increasing and relative risk reduction decreases, the ICER increases and the cost-effectiveness of the strategy, Common practice + Ably Bed declines.

Figure 9 Two-way sensitivity on relative risk reduction of the Ably Bed, on HAPU of both severity groups.

Row values are input parameters for the relative risk reduction of HAPU I/II and the % incline / decline from base case relative risk reduction. Column values are input parameters for relative risk reduction of HAPU III/IV and the % incline / decline from base case relative risk reduction. The values in the shaded area are ICERs. Red area represents ICER above a WTP threshold of NOK 200 000, yellow area are ICERs above the base case ICER of NOK 41 215, and green area are ICER below NOK 41 215.
Figure 10 shows the resulting ICERs when the cost and probability of complication is changed simultaneously. The analysis yields ICERs much closer to the base case ICER of NOK 41 215 than the previous two-way sensitivity analyses. As the probability of a complication and the price of complication both increases, the ICER declines, indicating that the strategy is increasingly cost-effective compared to common practice alone.

**Figure 10 Two-way sensitivity on complication.**

Row values are input parameters for the cost of complication, column values are input parameters for the probability of complications. Numbers are showing ICERs corresponding to each of the values of the input parameters, Cost of complication and Probability of complication. There are no values above NOK 200 000, hence no red shaded ICERs. Yellow area are ICERs above the base case ICER of NOK 41 215, and green area are ICER below NOK 41 215.

**Probabilistic sensitivity analysis**

Figure 11, the CE-plane, illustrates the results from the 2000 probabilistic simulations. The majority of the ICERs from the simulation are located in southern part of the CE-plane, indicating that the strategy, Common Practice + Ably Bed, is less costly than common practice alone. However, a larger share of the ICERs are located in the south-west quadrant, representing outcomes where the strategy is less costly, but also less effective. The ICERs in the south-east quadrant represent dominating ICERs. For the simulated ICERs in the north-east quadrant there will be a trade-off between increased costs and more effect. In the south-west, there is a trade-off between having to pay less and generating less QALYs. There are also simulated ICERs falling in the north-western corner, which indicates that there is a probability that Common Practice + Ably Bed will both cost more and generate less effect than common practice only.
All ICERs falling below the WTP-threshold line is to be considered as cost-effective, as they represent outcomes that are below the society’s WTP threshold for additional QALYs. The probability that each of the strategies will be considered as cost-effective is estimated and presented by cost-effectiveness acceptability curves in Figure 12. At a WTP-threshold of NOK 0,00 the two strategies have an equal probability of 50% for being cost-effective. At a threshold of NOK 50 000, Common practice have a 55% probability, while Common Practice + Ably Bed have a 45% probability of being cost-effective. As a large part of the ICERs from the simulation are located in the south-west and north-west quadrants, the probability of Common Practice + Ably Bed being cost-effective compared to Common Practice only, will not reach a 100% regardless of a threshold close to infinite.
Figure 12 Cost-effectiveness acceptability curves resulting from PSA.

Illustrating probabilities for each of the strategies being cost-effective for different threshold ICERs. Probabilities are on the y-axis and the different threshold ICERs are on the x-axis. The green line is the CEAC of the strategy Common Practice + Ably Bed, the blue line is the CEAC of the strategy common practice only.

5.2 Headroom analysis

As the headroom analysis was based on different scenarios, the headroom, or efficiency gaps for cost-effectiveness calculated, differ depending on several factors. It is however, reasonable to believe that the calculated gaps for efficiency are large enough for Ably Bed to be a cost-effective technology.

The expected net reduction in health care costs, calculated by applying the decision-tree model and subtracting the cost of Ably Bed per patient, for each patient pathway, is – NOK 610 per patient admission, when switching from Common Practice only to Common Practice + Ably Bed. This is equal to the net benefit for the health care provider for each patient that is placed in an Ably Bed. During a beds 10 years life time, the total net reduction in HCC is NOK 530 090 with an average LOS of 4.2 days, and NOK 148 230 with an average LOS of 15 days. Figure 13 illustrates the estimated maximum price the health care provider will be willing to
pay (MRP) for the Ably Bed per patient. With a threshold ICER of NOK 200 000 and NOK 300 000, the MRP is NOK 394 and NOK 494 respectively. This result is relatively close to the base case value used in the CUA, which is NOK 237, and where the sensitivity analysis, illustrated in Figure 8, shows that the ICER is NOK 200 540 for a price per patient of NOK 403.

Figure 13 CE-plane with maximum reimbursable price (MRP) of the Ably Bed per patient, with a threshold ICER of NOK 200 000.

Net cost reduction: cost of treatment if Ably Bed is provided free of charge. Gain in QALYs is per patient admission. Incremental costs is on y-axis and incremental effect is on x-axis. Red dotted line represents a WTP threshold of NOK 200 000.

The results from Headroom analysis are presented in Table 9. Assuming that the bed is fully functioning for 10 years and it is used by 86.9 patients each year (with an average LOS of 4.2 days), the Headroom estimate, which is equal to the MRP, for one Ably Bed was estimated to be NOK 516 186. When average LOS is assumed to be 15 days, the Headroom estimate is NOK 144 342. With a threshold ICER of NOK 300 000, the Headroom is NOK 603 086 and NOK 168 642 for average LOS of 4.2 and 15 days respectively. There are very large values net of production costs for the company in continuing developing the product. For the two first years only, when the company plan on selling approximately 3 100 beds in total, for a price of approximately NOK 200 000 per bed, and unit production cost is NOK 97 000, the value net of
production costs, \( V \), is ranging from the most conservative estimate of NOK 146,760,200 to the most optimistic, NOK 1,568,866,600, depending on the Headroom estimate.

<table>
<thead>
<tr>
<th>Table 9. Headroom analysis of the Ably Bed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculations are based on two different WTP-thresholds and two different LOS.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average LOS 4.2 days</th>
<th>Average LOS 15 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \lambda = \text{NOK 200,000} )</td>
<td>( \lambda = \text{NOK 300,000} )</td>
</tr>
<tr>
<td>Headroom estimate, ( H )</td>
<td>NOK 516,186</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year 2019-2020</th>
<th>NOK 1,299,476,600</th>
<th>NOK 1,568,866,600</th>
<th>NOK 146,760,200</th>
<th>NOK 222,090,200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 2019-2022</td>
<td>NOK 9,683,196,600</td>
<td>NOK 11,690,586,600</td>
<td>NOK 1,093,600,200</td>
<td>NOK 1,654,930,200</td>
</tr>
<tr>
<td>Year 2025</td>
<td>NOK 11,679,650,000</td>
<td>NOK 13,852,150,000</td>
<td>NOK 2,383,550,000</td>
<td>NOK 2,991,050,000</td>
</tr>
</tbody>
</table>

\( \lambda \) represents the WTP threshold. \( H \) is representing one Ably Bed during its total lifetime. \( M \) represents sale quantities per year. \( U \) is the unit cost of production. Year 2019-2020 \( U = \) NOK 97,000, \( M = 3 \) 100. Year 2019-2022 \( U = \) NOK 97,000, \( M = 23 \) 100. Year 2025 \( U = \) NOK 49,000, \( M = 25 \) 000.

5.3 Stakeholder interviews

The main driver for uptake of innovative technologies is partnership between suppliers and the health care institutions, which allow for collaboration in both development and testing of new technology. The main factors for decision-making regarding procurement of medical devices are the price of the technology, the quality of the product and whether the technology is well known and tested. Some of the needs related to patient beds are ease of use, fully electronic, integration with other equipment such as wheel chairs, and an automatic cycle of pressure alternation, and a bed equipped with a mattress suitable for patients at risk of PU.

5.3.1 Procurement of medical devices

The result from the analysis of the interviews, on the topic procurement of medical devices, are presented in Table 10. In total, there are six categories belonging to this topic. Decisive factors for decision making concerning investment in medical technology, innovative procurement and value-based procurement are categories developed prior to the interviews and which the
questions related to procurement are based on. The categories; user needs, competition and implementation are emerging from the analysis of the interviews. As the respondents are employed in Norway, the processes described and the results from the interviews are based on a Norwegian perspective.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Categories</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement of medical technology</td>
<td>User needs</td>
<td>Procurement planning is based on identified user needs. A list of needs is sent out from the health care providers to the procurement managers, who plan the investments for the upcoming year.</td>
</tr>
<tr>
<td>Competition</td>
<td></td>
<td>Competition in procurement is required. Procurement processes are therefore based on open tenders.</td>
</tr>
<tr>
<td>Decisive factors</td>
<td></td>
<td>Discrimination is generally not allowed. Health care providers can therefore not ask for a specific device from one specific supplier.</td>
</tr>
<tr>
<td>Value-based health care</td>
<td></td>
<td>A new concept in procurement of medical devices. For procurement, value is introduced through the concept “value-based procurement”.</td>
</tr>
<tr>
<td>Value-based health care</td>
<td></td>
<td>Yet to be fully implemented</td>
</tr>
<tr>
<td>Value-based health care</td>
<td></td>
<td>Value-concept implemented in profit calculations by applying a broader perspective</td>
</tr>
<tr>
<td>Innovative procurement</td>
<td></td>
<td>Procurement through partnership and collaborative product development</td>
</tr>
<tr>
<td>Innovative procurement</td>
<td></td>
<td>Positive discrimination of supplier allowed</td>
</tr>
<tr>
<td>Innovative procurement</td>
<td></td>
<td>Risk related to investment in innovation is shared between the parties</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td>Innovative technology may require a restructuring of working environment</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td>Reorganization of task performance</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td>Cooperation between different types of professionals</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td>Additional staff required</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td>Need of training</td>
</tr>
</tbody>
</table>
Procurement based on user needs:

Procurement of medical devices is based on the need of the health care providers, and the users of such devices. Users are often the health care providers themselves but can also be patients. At the end of each year, the hospitals provide the procurement management with a list of what equipment they need for the upcoming year. Procurement management is then, together with management at the hospitals setting prioritizations and making decisions on what technology to invest in during the upcoming year. As procurement is based on the needs of the users, be it health care providers or patients, developers of medical technology must ensure that their technology is in fact addressing a need.

“It is during the hospitals own planning process it is identified what investments that are to be done, presented in a yearly plan” (Procurement manager)

“The users very often know what they want, as they are aware of their own needs” (Procurement manager)

“Each year a wish list is sent out where we state what we see we are missing. It is sort of like an application on what we need, why we need it and what we wish to accomplish with the equipment” (Health care provider no. 1)

Competition based procurement:

There are formal requirements concerning the procurement of medical technologies in the Norwegian health care sector, such as the requirement of competition (Anskaffelsesloven, 2016 § 4). Developers of medical technology may be facing a high degree of competition, despite having a unique product, as open tenders are required.

“We who work with procurement are very concerned that we do not favorize anyone or wish for a specific supplier to win the bid, even though we have negotiations. We are very concerned about securing a good competition and open bidding processes” (Procurement manager)

The requirements for the technology to be invested in, is also determined by the users. Requirements can be related to user experience, or more specific requirements such as size and weight that might be relevant for the facilities in which the device is to be used. Procurement managers align these requirements with the regulations to ensure competition is intact.
“They cannot make requirements that discriminates suppliers. If they set requirements that are fulfilled by one supplier only, we step in and tell them that this is not something they can require” (Procurement manager)

“We try to make them describe their needs instead of than specific products. We are always trying to talk in terms of needs rather than products with the users” (Procurement manager)

Factors for the decision making:

The three respondents all mentions price as an important factor in the decision-making process. The two health care providers both states that price is the single most important factor. Quality of product seems to be the second most important factor. Other important factors are related to user experience and whether the technology is tested and well-known. Open tenders and bidding processes yields competition based on price, the difference in effect have to be substantial for a more expensive device to win the bid.

“It is the price that determines it” (Health care provider no. 1)

“Optimally, we want the best equipment. But independent of quality, the price will be decisive. If there is a price difference, the effect has almost to be about death-no-death” (Health care provider no. 1)

“I think a lot is based on price, and hopefully also on function. But a large part is most likely based on the price. If you have two relatively equal products, you would choose the cheapest one because it has the same function” (Health care provider no. 2)

“A lot is based on which supplier can provide the cheapest alternative, unfortunately” (Health care provider no. 2)

Second most important factor for decision-making concerning procurement of medical devices, is the quality of the product. It is not clear whether quality here is meant as durability of the device, user satisfaction or the effectiveness in terms of generating additional health utility.

“Price means a lot, but quality counts as well” (Health care provider no. 1)

“Price is normally just 35-50% weighted, the rest is quality and ergonomic” (Procurement manager)
Although price is stated to be the main determining factor in the investment decision, evidence does seem to matter. Both health care providers state that their health care organization are concerned about whether the device is tested and well known. This is in line with quality being an important factor. For quality in terms of effectiveness to be proven, clinical testing and technology assessment have to be done. The procurement of innovative technology requires evidence from clinical studies.

“I believe they would choose the product that is well tested and used earlier” (Health care provider no. 2)

“Of course, if there have been done quality studies where it is compared to other technology which is of almost the same price, then I believe that it matters” (Health care provider no. 1)

“I do not know if we receive information from clinical studies regarding the hospital beds, but it would not hurt” (Procurement manager)

“We are quite restrictive when it comes to trying the newest technology. We want evidence of it working first” (Health care provider no. 2)

“Especially for new products and untested technology, we would require clinical studies” (Procurement manager)

**Value-based procurement:**

Value-based procurement is introduced but is yet to be fully implemented and utilized as a way of making decisions regarding investments in technology. However, certain elements of value is used, such as applying a broader perspective when performing profit calculations.

“The CEO of Sykehusinnkjøp is very fond of value-based procurement. We also have a team who is working with this, in order to implement it into our processes and put more weight on the value rather than the price” (Procurement manager)

“We have decided to take into use the philosophy of value-based procurement, but it has not yet been implemented into our tools” (Procurement manager)

“We have tried to make the profit calculations a little broader in terms of trying to calculate whether we are saving some full-time employees for the hospitals. Whether
they are able to work more efficiently with the products we are buying” (Procurement manager)

Having the right medical devices and enough equipment, along with appropriate staffing and high competent care givers, are considered essential for being able to provide care that is of good quality, and thereby generates more value to the patient. Value-based health care can be about managing based on quality of care rather than budgets and financials only.

“From the perspective of a nurse, value-based health care is about a leader who understands that one need the necessary in order to provide good care, and often more than what is the standard” (Health care provider no. 2)

Innovative procurement:

Innovative procurement is a new type of procurement process for Norwegian public procurement. It is a set of methods and tools, developed to improve the coverage of user needs in a procurement process. It is a process that is concerned about facilitating innovation through dialog and partnership with suppliers. Innovative procurement is yet to be fully implemented into the procurement process of medical devices. It is stated that this is an important process for ensuring that new technology is taken into use, but it is not believed to be an arena for large volume procurement.

“Innovative procurement is procurement where you enter into partnership with typically an entrepreneurial company who are developing a product especially for you, and where you are allowed to positively discriminate them afterwards” (Procurement manager)

“We do not have much experience with innovative procurement. I don’t believe we have done such a type of procurement yet” (Procurement manager)

“I believe it plays an important role in bringing forth new technology, but I don’t believe it will be big in volume” (Procurement manager)

Procurement of new technology and innovative products are often a result of a partnership between the users and developers of medical technology. Through testing, a collaborative product development and risk sharing, innovative technology is reaching the health care providers as the degree of competition is reduced by allowing for positive discrimination of
suppliers. For developers of highly innovative devices and technology, partnership is the key for ensuring technology uptake, as it allows the users to participate in the testing.

“It’s about supporting the development of new products, and us taking part of the risk from the developer by promising that we will buy the product afterwards” (Health care provider no. 1)

“We have bought quite a lot of medical devices that are relatively new and partly untested, in order for us to test it ourselves and on our own patients” (Health care provider no. 1)

“We have bought equipment after participating in projects where we have tested products together with the developers” (Health care provider no. 1)

“We have our own data because we have tested the technology together with the developer and some of the technology we end up buying, for a reduced price afterwards” (Health care provider no. 1)

**Implementation barriers of new technology:**

New technology may require training of staff to ensure compliance with the device. Moreover, additional staff may be needed. Working environments and the organization of collaboration between different hospital wards or different type of staff and professions, may need to be modified. This causes barriers for technology uptake.

“We see that a lot of the new technology is beneficial for the patients, but requires additional staff” (Health care provider no. 1)

Implementation of the Ably Bed could lead to a need of re-organization to ensure compliance and a high degree of utilization.

“A hospital bed of the sort like Ably Bed, will most likely require some restructuring at the hospitals. It will always be difficult to change established routines” (Procurement manager)

“Such a bed will require a restructuring of routines and structures so that the bed is always in use. This is the thing that most often stops innovative products, because it requires a restructuring of internal routines” (Procurement manager)
5.3.2 Pressure ulcers

The results from the analysis of the stakeholder interviews on the topic, pressure ulcers, is presented in Table 11.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Categories</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure ulcers</td>
<td>Prevention</td>
<td>Individualized prevention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Appropriate underlays</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Frequent turning of patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin assessment and skin care</td>
</tr>
<tr>
<td></td>
<td>Nutrition</td>
<td></td>
</tr>
<tr>
<td>Procedures</td>
<td>Guidelines in Patient Security Program</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Should start as early as possible</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renting of underlays from companies when needed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Optimization of patients for elective care to reduce risk</td>
<td></td>
</tr>
</tbody>
</table>

Prevention:

When asking the health care providers about how pressure ulcers can be prevented, they list quite a few important methods and things to consider when a patient is admitted to a hospital. The method stressed the most is; daily skin assessment, good mattresses and pillows, regular and frequent changes in positions, avoidance of moisture, appropriate nutrition, physical activity and optimization of patients before admission (elective care).

“Advices are adapted to the individual patients. But most importantly, they need good mattresses, good chairs and good pillows in their wheel chairs” (Health care provider no. 1)

“They need to be able to change their positions. We want changes in positions four times per hour” (Health care provider no. 1)

“We are saying that the best mattresses we use are the alternating pressure ulcer mattresses, where the air in the mattress changes” (Health care provider no. 1)
“Research is showing that patients in risk of developing a PU, or already have a PU, should be placed on something else than a standard mattress” (Health care provider no. 2)

**Procedures:**

Lack of time to perform proper risk assessment and prevention of HAPU is a problem. Especially in acute care and in emergency wards, prevention is downgraded due to lack of time. Prevention should start within the first few hours after admission, as admission often starts at the emergency wards, where prevention of HAPU is not prioritized, proper prevention may not be carried out.

“It is common to rent alternative pressure ulcer mattresses from companies, but this is affecting the budgets for the specific department. Those departments with a lot of high risk patients, spend a large part of their budget on renting those mattresses” (Health care provider no. 2)

*We are supposed to work according to principals of the patient security program where it is stated that skin assessment is to be done within the four first hours after admission. But many do not have the capacity to do this at the emergency rooms because there is so much happening there, and they do not prioritize it” (Health care provider no. 2)*

“Elective patients should be in a better shape and one can therefore plan and optimize the patient before admission” (Health care provider no. 2)

“Prevention should actually start already in the ambulance on the way to the hospital. It cannot start early enough. But yes, we start as soon as they are admitted” (Health care provider no. 1)

**5.3.3 Ably Bed**

The result from the analysis of answers to questions related to the topic, the Ably Bed, is presented in Table 12.
Table 12. Results from the analysis on the topic, Ably Bed

<table>
<thead>
<tr>
<th>Topic</th>
<th>Categories</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ably Bed</td>
<td>Requirements (need to have)</td>
<td>Ease of use and maneuvering</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Durable</td>
</tr>
<tr>
<td></td>
<td>Preference (nice to have)</td>
<td>Safe</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fully electronic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Integrated with wheel-chair for safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pressure redistribution cycle to reduce need for turning of patient during night</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screen with data next to bed to follow own movement frequency</td>
</tr>
</tbody>
</table>

**Requirements:**

The health care providers state quite similar requirements for a hospital bed. It has to be easy to change the position of the bed up and down, and easy to get in and out of. Moreover, it is important that the bed is easy to maneuver and not too heavy. It is also important that it can endure rough use, cleaning and disinfection by the use of machines and high temperature water.

**Preferences:**

Turning of patients are time consuming, and disturbs the sleep of the patients, automation of pressure redistribution is mentioned as a technology attribute that would be of interest.

“I’m thinking that if everything could be electrical, the changing of the settings and lifting of the patient. And if the patient could lay in the bed in the night and tilt a little from side to side in order to get the necessary changes in position by setting a timer to change positions every other hour or something, without disturbing their sleep, this would be very good” (Health care provider no. 1)

“The data collected from the sensors in the bed should be visible on a screen next to the patient because patients don’t believe it themselves how little they are moving, and this would make it easy for them to track it” (Health care provider no. 2)

The health care providers seem to be curious to whether the bed can replace the alternating pressure mattresses or whether the two technologies should be combined to ensure optimal
effect. It is suggested that Ably Medical tests the bed by using different types of mattresses before entering the market.
6 Discussion

By applying the framework of early HTA, this thesis contributes to the decision-making concerning further development of the Ably Bed, by informing the developers about whether the technology has a potential for being cost-effective. Moreover, it highlights some of the issues medical technology companies will face during the process of bringing a new product to the market. Many decisions have to be made along the way, and with a finite budget, knowledge is key to making the right decisions.

6.1 Main findings

The findings from the CUA indicated that the Ably Bed has a potential for being cost-effective. There are however, substantial uncertainty surrounding the result. The findings from the headroom analysis was in line with those of the CUA. Although the headroom, or gap, for cost-effectiveness was not too high, it was considered to be large enough for the Ably Bed to have a potential for being cost-effective. The value of return on investment for Ably Medical and investors is estimated to be very large. Finally, success on the market will depend on the price and ease of implementation, technology uptake may therefore be challenging for an innovative hospital bed, such as the Ably Bed.

6.1.1 Cost-utility analysis

The results from the CUA analysis indicated that Common Practice + Ably Bed has a potential for being a cost-effective strategy for the prevention of HAPU, compared to the strategy, Common Practice only. The model sensitivity to uncertain input parameters was tested through deterministic sensitivity analysis. The result proved robust to some of the parameters tested, but sensitive to others.

The probability of developing a HAPU of grade I/II when admitted to hospital was considered a highly uncertain parameter, as research has shown that the prevalence rate varied between hospitals, wards, and patient groups (Bredesen et al., 2015). The 50% reduction from the base value of a 13% probability, resulted in an ICER above a WTP threshold of NOK 200 000.

The relative risk reduction of developing HAPU of either group, when placed in an Ably Bed were highly uncertain values, as they were not based on evidence from clinical testing, but
rather target goals of Ably Medical. The relative risk reduction for HAPU I/II had the largest impact on the result and the model was not robust to a 10% reduction in the relative risk. When the relative risk reduction of HAPU I/II was reduced down to 1%, the resulting ICER was NOK 261 581. The model did not prove robust to changes in the parameter for HRQoL utility value of being HAPU free.

The price of the Ably Bed per patient was considered as a highly uncertain value. The parameter was raised by 500% from the base value in order to reflect the fact that the unit sales price of the Ably Bed, the degree of utilization and life time of the bed are all factors impacting the parameter. The resulting ICER was as high as NOK 1 179 247.88. The result was found to only be robust to increases of 10-20% from the base value of NOK 237, when all other parameters were hold constant.

The model was also tested for sensitivity in parameters by the use of two-way sensitivity analysis. The result was sensitive to simultaneous changes in the relative risk reduction of HAPU I/II and the price of the Ably Bed per patient. As the price increased and the relative risk reduction was reduced, the ICER increased to unfavorable levels. At the base case price of the bed per patient, the relative risk reduction had to be no less than 2% for Common Practice + Ably Bed to remain cost-effective. The model is also sensitive to changes in relative risk reduction for both groups, when relative risk reduction is reduced to 1%. The model proved robust to simultaneous changes in the cost and probability of complications. Overall, the model was robust to changes in the parameters of +/- 10%, with the exemption of a 10% reduction in relative risk reduction of HAPU I/II.

The PSA showed that there is a high probability of making the wrong decision. The probability that the ICER would be accepted and that Common Practice + Ably Bed would be the optimal strategy was only 45%.

### 6.1.2 Headroom analysis

The Headroom analysis showed that, with a WTP threshold of NOK 200 000 and NOK 300 000, the parameter for the price of Ably Bed per patient, could theoretically be increased up to NOK 394 and NOK 494, respectively. There were several possible Headroom estimates calculated, ranging from the most conservative estimate of NOK 144 342 to the most optimistic estimate of NOK 603 086 per patient bed. The estimated headroom for cost-effectiveness may
not be sufficient to cover both development and production costs per bed. However, the headroom estimates calculated based on the LOS of 4.2 days are promising as they imply MRPs above NOK 500 000, which shows that the planned unit price of the bed of NOK 200 000, could potentially be increased by more than NOK 300 000, and still reimbursable. Furthermore, the result from the calculations of the value of revenues net of production costs, $V$, showed that there are substantial values, across all calculated headroom estimates. Only the first two years, the values net of production costs, given that the company can sell 3 100 units, ranges from the most conservative estimate NOK 146 760 200 to the most optimistic, NOK 1 568 866 600. If Ably Medical can reach the sale level of 25 000 beds sold yearly, the values net of production cost, ranges from NOK 2 383 550 000 up to NOK 13 852 150 000, depending on the Headroom estimate.

6.1.3 Stakeholder interviews

The three stakeholders interviewed did not have equal views on what factor is the most important in a decision-making process regarding procurement of medical devices. Although the procurement manager stated that the price only counts approximately 35%, the two health care providers opinion was that price is the decisive factor. Moreover, quality of the product and whether the technology fulfill the needs of the users, were stated as important factors. Whether the technology is well known and tested seems to have an impact on the procurement decisions. Partnership between developers and users often result in technology uptake of more innovative technology. Finally, new procurement regulations which allows for positive discrimination of developers of medical technology, may have a positive impact on the uptake of innovative medical technologies.

Prevention of HAPU is both costly and time consuming. The health care providers stated that lack of time to perform proper prevention of HAPU was a problem, especially in acute care. Health care provider needs concerning prevention of HAPU are appropriate underlays and more time to do frequent turning of patients as well as regular skin assessment and care. These are in line with the methods for prevention used in the study by Schuurman et al. (2009) from which the cost parameters for the CUA were taken from. Specific for patient beds, needs mentioned were a fully electronic bed, integration with other equipment such as wheel chairs to enhance mobility and safety of movement. Moreover, an automatic pressure redistribution cycle would save time and improve night sleep. Lastly, patients should be able to follow their own data on
a screen to track their own frequency of movement, and thereby be more involved in the prevention of HAPU.

### 6.2 Previous research

The Ably Bed is a unique product and it has therefore not been done studies on patient beds with the exact same technology. However, there do exist high-technology patient beds designed especially for intensive care patients, who have a higher risk of developing HAPUs, and which reduce the risk of HAPUs by redistributing pressure. Although this is, to our knowledge, beds that are equipped with e.g. special air mattresses or high specification foam mattresses, the concept of reducing risk by redistributing the pressure, is the same as of the Ably Bed. Fleurence (2005) suggests that pressure alternating mattresses are cost-effective for treatment of PU, whereas pressure alternating overlays are cost-effective in the prevention. Padula et al. (2011) found in their research on cost-effectiveness of HAPU prevention, that prevention is cost-effective compared to standard care, when assuming an odds ratio of preventive HAPU incidence of 0.335.

Chapman et al. (2014) found in their research on early HTA as a framework for informing decision of medical device development generally, and headroom performance specifically, a low specificity of the headroom method. For devices that did not reach technology uptake by the NHS, only 67% was determined as unfavorable by the headroom method. This implies that there is no guarantee of technology uptake of medical devices that are deemed favorable by this method. Headroom was also found to usually be calculated for only one area although a device could be applied in multiple areas of care. Evidently, calculating the headroom of the Ably Bed as a preventive device for HAPUs only, may be considered appropriate. Moreover, Chapman et al. (2014) argue that the method should be used to ‘rule-out’ only those devices that will for certain never be deemed favorable, and should not be used to reject investment in technology that may have a chance for uptake. Innovators of medical technology may have little to no experience with economic evaluations, the simplicity of the Headroom method allows for estimations of cost-effectiveness without any knowledge to health economics. Furthermore, the method has found to be useful in informing decisions related to entering new markets, or to communicate potential value of an investment to potential investor (Chapman, 2012).
A key factor for the likelihood of technology uptake of medical devices, is whether the product will be reimbursed. For a product to be reimbursed, it must be included in the DRG system. For innovative products, DRG codes may not exist for the technology in question. The likelihood of technology uptake of highly innovative product will therefore depend on the frequency of revision of the DRG codes (Torbica and Cappellaro, 2010). The process for procurement is another important factor for technology uptake. In procurement with competitive bidding processes, the suppliers of medical technology will end up having to compete on price, leaving quality as the secondary factor for decision making (Torbica and Cappellaro, 2010). This is in line with the findings from the analysis of the stakeholder interviews. A systematic literature review on the determinants of medical technology adoption, found economic and clinical relative advantages to be key factors. Compatibility with the working environment and sufficient evidence, along with supplier promotion were also important determinants. Moreover, as of organizational determinants, large teaching hospitals tend to be early adopters of medical technology (Varabyova et al., 2017). This finding contradicts what was stated by one of the informants in the interview, where larger hospital was said to be less willing to invest in new and unknown technologies compared to smaller hospitals.

An important distinction between medical devices and pharmaceuticals, concerning the assessment of health technology, is the learning curve and incremental innovation. Medical devices have higher implementation barriers due to i.e. the requirement of changes in working processes or time to develop skills in performing care by the use of the new technology. The overall outcomes in terms of health and cost of care may depend on the skills in operating the technology. Moreover, medical devices tend to be regularly updated with new features. The assessment of such devices is therefore complex. Tarricone et al. (2017) found in their research on improvement of methods for economic evaluations of medical devices, that the impact of learning curve, incremental innovation and organizational aspects of implementation were rarely included in the assessment, although this may impact the resulting cost-effectiveness level. They suggest that post-market studies and appropriate techniques for adjusting for biases would reduce the uncertainty surrounding the assessment result of medical devices. Moreover, they argue that this will improve decision making regarding investment and reimbursement of medical devices, as policy- and decision makers can take better informed decisions (Tarricone et al., 2017).
6.3 Interpretation of results

In total, across the wards in Norwegian hospitals, Bredesen et al. (2015) found the percentage of patients at risk to be 25.2%. This implies that if a hospital has a population of 10 000 patients over a time period of 1 year, across wards, approximately 2 520 patients will be at risk of developing a HAPU, and therefore be in need of preventive care. Given that the Common Practice + Ably Bed is cost-effective compared to Common Practice only, the strategy will generate 2.52 QALYs more, for an increase in costs of NOK 108 360 over 1 year. This result would fall below a WTP threshold of NOK 200 000 per QALY with good margins.

The model was most sensitive to the relative risk reduction of HAPU I/II, probability of HAPU I/II and the cost of Ably Bed per patient, and less sensitive to changes in the parameters for costs of treatments and complication. The model result is therefore believed to be driven by the cases of HAPU prevented and the reduced costs this impose on the health care provider. Naturally, as the probability of HAPU increases, the relative risk reduction associated with the Ably Bed will have a higher impact as more cases can be averted. The sensitivity analysis is based on a WTP threshold of NOK 200 000. A higher threshold would imply different results from the analysis. By increasing the threshold up to NOK 300 000, the model is robust to a change of +/-50% in all the parameters, including the price of the Ably Bed per patient. If the threshold is set to NOK 500 000, a fairly normal WTP threshold in the Norwegian health care sector (Woods et al., 2016), the price of the Ably Bed per patient can increase up to NOK 711 (200% increase from base value) and still generate an acceptable ICER.

The result from the headroom analysis is likely to be over optimistic as the Headroom method tend to yield overestimated results (Chapman et al., 2014). The actual headroom for cost-effectiveness and the MRP should therefore be expected to be below the estimated values. Furthermore, one cannot expect the actual sales price to equal the MRP due to procurement being based on competitive tenders. Although the estimated headroom may not be sufficient to cover both development and production costs, looking at the estimates of the potential value of sales net of production, investment in further development to bring the product to the market is advised because of the potentially very high values of sales net of production costs. Moreover, the estimated headroom and MRP, may in fact be conservative in this analysis, as the WTP thresholds used is relatively low. For a WTP threshold of NOK 500 000, the headroom would
be substantially larger, implying a larger gap for cost-effectiveness, and hence a more commercially viable technology.

Value-based procurement is believed to play an important role in achieving value-based health care (Prada, 2016). Setting a price according to the estimated Headroom would imply pricing according to WTP for effect, which is a value-based pricing strategy. However, the stakeholder interviews revealed that value-based procurement is yet to be implemented. It may therefore be challenging for Ably Medical to succeed with a value-based pricing strategy, as procurement is still for the most part concerned about the unit price of devices. Although quality is taken into account in the decision, it does not necessarily mean that this is to be reflected in the price of the device.

The stakeholder interviews revealed that technology uptake for the Ably Bed is not guaranteed. Procurement of medical devices is based on the need of the users. Innovative technologies must therefore address a need to be taken into use. However, there are many examples of highly innovative products, which doesn’t succeed in the market because it fails to address the actual need of the users. It was mentioned by the procurement manager interviewed, that the Ably Bed might address needs which the health care providers and users may not know that they have. As the Ably Bed is more than a standard patient bed, it addresses several needs in one product, however, this may imply that open tenders are difficult to win, as the procurement may not be based on multiple needs simultaneously. There is a high degree of competition, which to a large extent is based on the price only. Going into partnership with health care providers might be the best way of introducing such an innovative hospital bed to the market, however, according to the procurement manager, smaller volumes and lower sales prices should be expected. The result from the Headroom analysis indicated that the maximum unit sales price that would be reimbursable was NOK 603 086. The most conservative estimate was NOK 144 342. However, Girling et al. (2012) argues that the unit sales price will most likely not be equal to this value, as it will normally lie between this estimate and the unit cost of production. The value of sales net of production costs will in reality therefore be less than what is estimated in the Headroom analysis. Moreover, if the Ably Bed can only achieve market access through innovative procurement, the sales volume could be smaller than what is projected by Ably Medical. This will in turn reduce the value of sales net of production costs.

As quality and evidence from clinical testing was found to be important factors in the decision-making regarding procurement, investment in HTA is recommended. The learning curve could
impact the resulting cost-effectiveness. This implies that partnership with potential users of the Ably Bed is even more crucial for proving effectiveness, and consequently achieve technology uptake and success in the market. Partnership with users may also solve the issue of aligning the needs addressed by the innovation and the needs of the users. Moreover, such a partnership may open up for the possibility to perform HTA research already at early stages, before the product is brought to market and consequently guide product development, rather than only guiding reimbursement from a policy perspective.

Vallejo-Torres et al. (2011) argue that early HTA contributes to value-based health by ensuring that only the potentially cost-effective devices are brought to the market. However, one could argue that early HTA may have an unwanted effect. Results from HTA will always be surrounded with some degree of uncertainty, and early HTA may be expected to yield results with an even larger degree of uncertainty, as it is conducted at a stage where less data will be available. Thus, basing important decisions regarding further development and investment in technology on information coming from early HTA is not risk free, as it could result in the wrong decision being made. Projects that would in fact have generated health value and become successful in the market, could be abandoned based on insufficient evidence. To avoid great innovations being abandoned, the information early stage HTA provides should be used with caution.

6.4 Limitations and future research

The research of this thesis is limited by several factors which are considered to have an impact on the result. A key limitation is the exclusion of two of the health care issues that the Ably Bed is being designed to improve. The technology’s potential impact on nurse load and risk of patient fall is left outside the scope of this thesis. All three analyses conducted, have therefore only considered the beds potential impact on PUs. The limitations relating to each of the three analyses will be addressed in further detail.

6.4.1 Cost-utility analysis

There are no clinical data on effect of the Ably Bed, and the analysis was therefore based on parameters from the literature and expert opinions. An important limitation is the fact that the CUA was not done from a specific setting. Although a Norwegian setting may have been
preferred, it was not feasible to extract Norwegian parameters from the literature as little to no research have been done on the cost of PU or effect of prevention. Parameters were therefore extracted from both European and US studies.

The estimates coming from Ably Medical are regarded as highly speculative values. The unit sales price is an estimation based on the prices of other high-tech patient beds. The cost of production will dependent on future decisions on how and where the bed will be produced. Costs related to the use of the bed, such as training and service have not been included, although they are likely to have an impact on the estimated cost-effectiveness level, especially as the stakeholder interviews revealed that ease of implementation and use was important for the health care providers. Moreover, the estimated unit price of the bed per patient will depend on the degree of utilization. The relative risk reduction was an assumption taken, in order to be able to model the effect. The relative risk reduction of the Ably Bed will depend not only on whether the technology works, but also compliance with the technology, in other words, whether it is used as intended. The learning curve will therefore impact both the total price of the bed, and the effect it has on HAPU. In general, cost components could have been calculated more sophisticatedly. All costs were adjusted for inflation but could also have been adjusted for purchase power parity, as numbers were extracted from several countries, with different currencies. Moreover, costs of complications were not weighted by the probability of experiencing each of the three complications included in the model, and may therefore be underestimated, as the most costly complication also had a higher probability.

The Ably Bed was only compared to common practice for prevention, which in practice can be a set of many different methods and interventions. Other technologies such as high specification foam mattresses or pressure alternating air mattresses could have been included. However, the cost parameter for common practice for prevention did include the cost of using such mattresses, which implies that they were indirectly included as a comparator. The analysis is considering the direct costs of prevention and treatment of pressure ulcers, only, leaving out the costs related to care for the condition that the patients are hospitalized for, as well as reimbursement according to the DRG system. The result is therefore showing the added costs for the health care provider when a patient is at risk of developing an ulcer and receives preventive care, as well as treatment if an ulcer develops.

As the analysis is concerning the prevention of HAPU specifically, and not PU generally, the analysis is done with the perspective of a hospital only, and not the health care sector as a whole.
This implies that the cost of other health care providers, such as GP, home care or nursing homes are not considered in the analysis. It could be argued that some of the cost components, such as the cost of death or part of the cost of treatment normally falls on health care providers in general, rather than specialized care. Some of the cost components in the model could therefore be overestimated. A societal perspective is often argued to be the optimal choice, as it includes both costs and effects from the intervention for the whole society, rather than the health care provider only. The Ably Bed is not designed to be used in hospitals only, in fact, the company is looking into opportunities in long term care as well. The appropriateness of using a perspective of hospitals only, could therefore be questioned. However, this perspective was chosen to keep the analysis within a reasonable scope for this thesis.

In a decision-tree model, time spent in each health state is not considered. HRQoL was therefore only measured at the end point. This implies that the utility the patient derives from being in the different health states during hospitalization and during each “arm” of the decision tree, is not captured by the model. As the severity of PU is divided into four different grades, and the HRQoL is decreasing with the severity of PU, a Markov model could be more suitable as it captures the transitions from one health state to another, when the severity changes or when complications or even death occur (Padula et al., 2011). Previous cost-effectiveness research found in the literature on PU was based on both types of models, and as this was an early stage HTA, the simplicity of the decision-tree was considered to be advantageous.

Additionally, there are several limitations related to the assumptions taken. As a patient admitted to a hospital is being treated for a health issue, he or she is likely to have a HRQoL utility level of less than 1 at admission. It may also be less than 1 at discharge, seeing as patient recovery normally continues after discharge from the hospital. All events in the model are assumed to occur during hospitalization. In reality however, they could happen after discharge.

No studies on the incidence rate of HAPU were found. Most research tend to be prevalence based, were the number of HAPUs at a specific point in time is counted. However, this number may vary greatly from day to day, depending on the population. The expert opinion which was used as the input parameter for the probability of HAPU stage I/II was based on an opinion which stemmed from prevalence rather than incidence studies. More research on the incidence rate of PUs in general and HAPUs specifically is therefore recommended, as this could provide important knowledge related to the risk and prevention of PU.
6.4.2 Headroom analysis

The Headroom method was conducted after the economic evaluation. Optimally, this type of analysis should have been conducted at the very early stage of planning and developing. However, basing the Headroom analysis on the CUA and applying the model for calculating the net health care costs may in fact have strengthen the estimations, as they are based on a more thorough analysis than what would otherwise have been the case. It is recommended to perform headroom calculations at several time points during product development, as new knowledge could generate new result. Ably Medical is therefore advised to recalculate the headroom for cost-effectiveness as more information is available on the beds impact on nurse load and patient falls. Additionally, we suggest applying the headroom method before entering the market, as it is a simple tool for estimating the MRP, and thus the starting point of the bidding process in a competitive tender.

Additional limitations of the headroom method and the analysis is that the sunken costs are not taken into account in this method. Moreover, the value net of production costs has not been discounted. It is therefore suggested to perform calculations of the net present value (NPV) of investment. The investment will be projected to be profitable if the NPV is positive. It is, important to acknowledge that the methods in the Headroom analysis are highly simplified. It is a framework best suited for calculating best case scenarios, and one should therefore interpret the results with caution. However, the simplicity of the methods is also what makes it such an easily applicable tool for fast decision-making, perfect for a start-up company like Ably Medical.

6.4.3 Stakeholder interviews

The most important limitation of the stakeholder analysis was the small number of respondents included. However, as this was intended to be an explorative rather than comparable analysis, few respondents and consequently less qualitative data was considered to not hamper the purpose of the study. Although the interviews were semi-structured, open ended questions generates opinion-based answers. If the same questions were asked to the respondents at a later time, they could have resulted in very different answers, as experiences are to a large extent relying on recent memory or a process where things did not go as expected. This could maybe explain why the two health care providers and the procurement manager had different opinions on what the decisive factor in procurement is. Another method which could have been applied
for eliciting the stakeholder preferences and needs is by the use of dichotomous choice models. Such a model would have been able to extract preferences for different attributes of the Ably Bed, with less risk of bias than open ended questions in a semi-structured interview.

The analysis of the interviews revealed that it may be difficult to achieve technology uptake for highly innovative products, and especially for technology that requires additional resources, adoption of the working environments to fit the technology, or re-organization of the interaction between different groups of staff. Moreover, innovative technology has a higher chance of uptake if the technology has been tested. It was mentioned that procurement of innovative technology often was a result of partnership with the developers. Ably Medical is already participating in a project together with the Canadian medical technology project MaRS EXCITE, and it is advised that that the company enters into similar projects in Norway and other markets where the company plan on entering, as this is expected to have a great impact on the success.
7 Conclusion

This thesis was conducted with the aim of applying a framework for early HTA, with the objective to inform Ably Medical about the Ably Beds’ potential for being a cost-effective, and successful technology on the market. By conducting an economic evaluation and calculating the headroom for cost-effectiveness, it was found that there is a potential for the bed to be cost-effective. Furthermore, the effectiveness gap is believed to be sufficiently large for Ably Bed to be a commercially viable medical technology. It is therefore recommended to invest in further development, as the potential future return of investment is high. This recommendation is based on an assessment of the technology where only the impact of PU was included. Future research is therefore recommended, with the inclusion of both patient fall and nurse load.

The research of this thesis has demonstrated that application of the early HTA framework is indeed feasible. By performing early HTA, medical technology companies can estimate the potential cost-effectiveness, and hence the value of the technology. The framework can contribute to giving the management of medical technologies a better understanding of the needs of the users and thereby align innovation with these needs. The application of early HTA, promotes the incorporation of value-based health care, not only at the demand and provision side of care, but also at the supplier side of health technology, throughout the development process. Because policy makers are slowly making a shift towards health care based on value rather than volume, and because of the high speed of innovation in the medical technology industry, cost-effectiveness of the innovation is believed to be an important factor for technology uptake and success in the market. Hence, innovators are advised to do technology assessment to ensure investments are done, only in those technologies that have a potential for being cost-effective.
References

ANSKAFFELSESLOVEN 2016. Lov om offentlige anskaffelser.


Appendix

ONE- AND TWO-WAY SENSITIVITY ANALYSIS

The figures below are showing the model sensitivity to the changes in the tested input parameters. All figures are presented with the tested parameter on the x-axis and the ICER on the y-axis. The curves in all figures are representing the ICER.

The model is sensitive to the changes in the probability of developing HAPU of stage I/II as the ICER increases to a level above NOK 200 000 when the probability of HAPU I/II reduces to 6.5%.

The relative risk reduction of HAPU stage I/II from being in the Ably Bed has a large impact on the ICER. A relative reduced risk reduction is associated with an increase in the ICER and vice versa.
The model is less sensitive to the changes in the parameter for relative risk reduction of HAPU III/IV. As the relative risk reduction is reduced to zero, the ICER does not however increase to unfavorable levels, as it is below NOK 200 000.

A reduction in the utility level of being free of PU is associated with an increase in the ICER. Although a 50% reduction in the parameter may be an exaggeration, the result remains cost-effective up to a reduction of 40% from the base value.

The result is robust to changes in the cost of treatment of HAPU I/II.
The result is robust to changes in the parameter for cost of treatment of HAPU III/IV.

The result is not sensitive to the probability of complication when having a HAPU stage III/IV.

A reduction in the utility of having HAPU III/IV with complication is associated with a decrease in the ICER.
The result is not sensitive to the cost of complication. A 50% change in each direction of the base case value has little effect on the ICER.

The model is close to insensitive to changes in the parameter for common practice of prevention.
# MODEL CALCULATIONS

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>DESCRIPTION</th>
<th>VALUE</th>
<th>Source</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>pHAPU_stage_I_II</td>
<td>Prob. of HAPU stage I/II</td>
<td>0.1300</td>
<td>Expert opinion</td>
<td></td>
</tr>
<tr>
<td>pNO_HAPU</td>
<td>Prob. of no HAPU</td>
<td>0.8700</td>
<td>Calculated</td>
<td>1 - pHAPU_stage_I_II (conditional probabilities)</td>
</tr>
<tr>
<td>pHealed_I_II</td>
<td>Prob. of HAPU I/II healed</td>
<td>0.6520</td>
<td>Calculated</td>
<td>1 - pRelapse_I_II - pPU_III_IV (conditional probabilities)</td>
</tr>
<tr>
<td>pRelapse_I_II</td>
<td>Prob. of relapse HAPU I/II</td>
<td>0.1155</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>pHealed_I_II._2</td>
<td>Prob. healed HAPU I/II after 2nd round with treatment</td>
<td>1.0000</td>
<td>Assumed</td>
<td></td>
</tr>
<tr>
<td>pPU_III_IV</td>
<td>Prob. of HAPU stage III/IV</td>
<td>0.2325</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>pPU_III_IV_healed</td>
<td>Prob. of HAPU III/IV healed</td>
<td>0.6977</td>
<td>Calculated from Padula et. Al 2011</td>
<td>1 - pPU_III_IV_relapse - pComplication - pDeath (conditional probabilities)</td>
</tr>
<tr>
<td>pPU_III_IV_healedABLY</td>
<td>Prob. of HAPU III/IV healed when placed in an Ably Bed</td>
<td>0.7845</td>
<td>Calculated</td>
<td>1 - pRelapse_I_II - (pPU_III_IV * pAB_HAPU_III/IV) (conditional probabilities)</td>
</tr>
<tr>
<td>pPU_III_IV_relapse</td>
<td>Prob. of relapse HAPU III/IV</td>
<td>0.0350</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>pComplication</td>
<td>Prob. of complication when HAPU III/IV is developed</td>
<td>0.1950</td>
<td>Calculated from Mathiesen et al. 2013</td>
<td>pcriticalColonization: 0.065 pCellulitis: 0.065 pOsteomyelitis: 0.065 Total: 0.195</td>
</tr>
<tr>
<td>pDeath</td>
<td>Prob. of death when HAPU III/IV is developed</td>
<td>0.0723</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>pAB_HAPU</td>
<td>Relative risk reduction of HAPU I/II when placed in an Ably Bed</td>
<td>0.7692</td>
<td>Estimated</td>
<td>0.1 / pHAPU_stage_I_II</td>
</tr>
<tr>
<td>pAB_HAPU_III/IV</td>
<td>Relative risk reduction of HAPU III/IV when placed in an Ably Bed</td>
<td>0.4301</td>
<td>Estimated</td>
<td>0.1 / pPU_III_IV</td>
</tr>
</tbody>
</table>
### HRQoL utility values

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>DESCRIPTION</th>
<th>VALUE</th>
<th>SOURCE</th>
<th>CALCULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>qWell</td>
<td>Utility when not having a HAPU</td>
<td>1.00</td>
<td>Padula et al. 2011</td>
<td>(adjusted to 0.99 for modelling purposes)</td>
</tr>
<tr>
<td>qStageI_IIHAPU</td>
<td>Utility when having a HAPU of stage I/II</td>
<td>0.78</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>qStageIII_IVHAPU</td>
<td>Utility when having a HAPU stage III/IV</td>
<td>0.60</td>
<td>Padula et al. 2011</td>
<td></td>
</tr>
<tr>
<td>qHAPU_Complication</td>
<td>Utility when having a HAPU stage III/IV with complications</td>
<td>0.51</td>
<td>Assumed</td>
<td>Reduced 15% from utility of having a HAPU of stage III/IV</td>
</tr>
<tr>
<td>qDeath</td>
<td>Utility when dead</td>
<td>0.00</td>
<td>Padula et al. 2011</td>
<td>(adjusted to 0.01 for modelling purposes)</td>
</tr>
</tbody>
</table>

### COSTS

**cTotal_treatment_I_II and cTotal_Treatment_III_IV**

Total cost of treatment of a HAPU stage I/II and HAPU III/IV

Deterministic value: NOK 4 198

Source: Schuurman et al. 2009

Calculation:

Source does not provide year of prices, prices are assumed to be from year 2008 and adjusted for inflation thereafter (19.9% from 2008 to 2017)

<table>
<thead>
<tr>
<th>Pressure ulcer grade</th>
<th>Mean treatment cost</th>
<th>Group average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>EURO 352</td>
<td>Group I/II: EURO 426</td>
</tr>
<tr>
<td>Grade II</td>
<td>EURO 500</td>
<td></td>
</tr>
<tr>
<td>Grade III</td>
<td>EURO 1232</td>
<td>Group III/IV: EURO 1 477</td>
</tr>
<tr>
<td>Grade IV</td>
<td>EURO 1722</td>
<td></td>
</tr>
</tbody>
</table>

Treatment cost consist of cost of repositioning, mobilization, wound care, special beds and mattresses, wound deressing, nutritional supplement and ointments.

Yearly exchange rate in 2008 from EURO to NOK: 8.2194

Converting to NOK:

- EURO 426 * 8,1294 = NOK 3 501
- EURO 1 477 * 8,1294 = NOK 12 140

Adjusting for inflation:

- NOK 3 501 * 1,199 = NOK 4 198
- NOK 12 140 * 1,199 = 14 556
HAPU I/II: NOK 4 198, HAPU III/IV: NOK 14 556

cTotal_CP
Total cost of providing common practice for prevention per admission.
Deterministic value: NOK 3 163
Source: Schuurman et al. 2009
Calculation:
Mean length of preventive care was estimated by Schuurman et al. 2009 to be 13.4 days. Price per day for prevention was EURO 24 (for an approach that focused on human resources, frequent turning, skin assessment etc.). Yearly exchange rate from EURO to NOK was 8.2194 in 2008. Price inflation adjustment 19.9%.
Mean total cost of CP per admission:
   EURO 24 * 13,4 = EURO 321,6
Converting to NOK:
   EURO 321,6 * 8,2194 = NOK 2643,36
Adjusting for price inflation:
   NOK 2643,36 * 1,199 = 3163

cAblyBed_per_patient
unit cost of Ably Bed per patient
Deterministic value: NOK 237
Source: Unit sales price estimated by Ably Medical AS
Calculation:
Ably Medical AS estimates the unit sales price of the bed to be USD 25 000. The bed is assumed to have a life time of 10 years. Mean LOS per admission is set to be 4.2 days (Statistics Norway, 2017). This gives 87 patients per year in the Ably Bed.
USD 25 000 / 10 years = USD 2 500
Yearly exchange rate in 2017 from USD to NOK was 8.263.
Converting to NOK:
   USD 2 500 * 8,263 = NOK 20657,5
Mean LOS: 4,2 days:

\[ \frac{365}{4,2} \approx 87 \]

Yearly cost of Ably Bed divided by the number of patients using the bed per year:

NOK 20657,5 / 87 \approx 237

Unit sales price in NOK: 206 575

Yearly cost in NOK: 20657,5

Price per patient: NOK 237

cRelapse_I_II

Cost of a relapse of HAPU grade I/II

Deterministic value: NOK 4 198

A relapse of HAPU implies a need for more treatment and an increase LOS. As no cost of relapse was found in the literature, it was assumed to be equal to treatment of HAPU grade I/II because patients need a second round with treatment to be healed. The parameter therefore consists of the same cost components as of the treatment of HAPU I/II. See cTotal_treatment_I_II.

cRelapse_III_IV

Cost of a relapse of HAPU grade III/IV

Deterministic value: NOK 14 556

A relapse of HAPU implies a need for more treatment and an increase LOS. As no cost of relapse was found in the literature, it was assumed to be equal to treatment of HAPU grade III/IV because patients need a second round with treatment to be healed. The parameter therefore consists of the same cost components as of the treatment of HAPU III/IV. See cTotal_treatment_III_IV.

cDeath

Cost of death

Deterministic value: NOK 12 774

Source: Mathiesen et al. 2013
Costs are from year 2011. Source does not provide information about the cost components of the parameter for cost of death. The parameter is however stated to be from the Danish DRG system. When looking up death in the Danish DRG system, death was found to have 3 different code\(^1\). Following the stated cost in the article, code 1503 was used: dead or moved to another department within two days, uncomplicated.


 Converted to EURO (in article): DKK 10 856 / 7,49 = EURO 1449,4

Cost of death: EURO 1449,4

 Yearly exchange rate in 2011 from EURO to NOK was 7,7926

Converting to NOK:

\[
EURO 1449,4 \times 7,7926 = NOK 11 294,59
\]

Adjusted for price inflation (13.1% from 2011 to 2017)

\[
NOK 11 294,59 \times 1,131 = NOK 12 774,18
\]

**Complication**

Cost of complication

Deterministic value: NOK 37 096

Source: Mathiesen et al. 2013

The study includes three different types of complications, critical colonization, cellulitis and osteomyelitis. Cost of complications in the study were based on the Danish DRG system. When looking up the costs in the DRG tariffs for year 2011, the corresponding codes was found to be:

Critical colonization and cellulitis - 0919: Infection in skin and under skin, patient at least 18 years of age: DKK 21 150

(assume that both critical colonization and cellulitis are in this code, as no other code was found to fit)

Osteomyelitis - 0877: Infections in joints and bones: DKK 54 344

Calculation:

\(^1\) DRG codes and tariffs from 2011 are available from: [https://sundhedsdatastyrelsen.dk/da/afregning-og-finansiering/takster-drg/takster-2011](https://sundhedsdatastyrelsen.dk/da/afregning-og-finansiering/takster-drg/takster-2011)
Critical colonization: DKK 21 150 / 7,49 = EURO 2823,77

Cellulitis: DKK 21 150 / 7,49 = EURO 2823,77

Osteomyelitis: DKK 54 3444 / 7,49 = EURO 7255,54

Cost was based on an average of the three:

\[ \frac{(2 \times 2823,77) + 7255,54}{3} = \text{EURO} \ 4301 \]

Yearly exchange rate in 2011 was 7.7926 from EURO to NOK.

Converting to NOK

\[ \text{EURO} \ 4301 \times 7,7926 = \text{NOK} \ 33 \ 516 \]

Adjusted for inflation (13.3% 2011-2017):

\[ \text{NOK} \ 33516 \times 1,133 = \text{NOK} \ 37 \ 906 \]
CONSENT FORM - PARTICIPATION IN RESEARCH

I volunteer to participate in a research project conducted by Agnes Karina Straum. The research is conducted as part of her degree in European Health Economics and Management at the University of Oslo. I understand that the project is designed to gather information about academic work. I will be one of approximately 3-4 people being interviewed for this research.

1. My participation in this project is voluntary. I may withdraw and discontinue participation at any time.

2. I feel uncomfortable in any way during the interview session, I have the right to decline to answer any question or to end the interview.

3. Participation involves being interviewed by the researcher, Agnes Karina Straum. The interview will last approximately 50-60 minutes. Notes will be written during the interview. An audio tape of the interview and subsequent transcript will be made.

4. I understand that the researcher will not identify me by name in any reports using information obtained from this interview, and that my confidentiality as a participant in this study will remain secure. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions.

6. I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study.

7. I have been given a copy of this consent form.

Date: Place:

________________________ Name printed

________________________ Name signed
INTERVIEW GUIDE – Procurement management

INTRODUKSJON AV INTERVJUER OG OPPGAVE

- Introduksjon av meg, Ably Medical og oppgaven
- Forklar formålet med intervjuet
- Opptak og transkribering av intervju
- Anonymitet, konfidensialitet og mulighet til å trekke seg

INTRODUKSJON AV INFORMANT

- Kan du fortelle kort hvem du er og hva du arbeider med?

INNKJØP AV MEDISINSK UTSTYR

- Kan du beskrive beslutningsprosessen for anskaffelse av medisinsk utstyr?
  a. Hvordan går dere frem?
  b. Hvilke kriterier eller faktorer blir det lagt vekt på i beslutningen?
  c. Hva vil du si er den viktigste faktoren i den endelige avgjørelsen?
- Hvilke krav setter dere til medisinsk utstyr og leverandører av slikt utstyr?
- Hvordan bruker resultatater fra kliniske studier og økonomisk evalueringer av medisinsk utstyr i en anskaffelsesprosess?

Innovasjon i helsesektoren

- Hva legger du i begrepet «innovativt innkjøp»?
- Hvordan mener du at innovative anskaffelser kan ha en betydning for helsesektoren?

Verdibasert helse

- Hva legger du i begrepeene «verdibasert helse» og «verdibasert innkjøp»?
- Hvordan arbeider dere med verdibaserte anskaffelsesprosesser?
- Hvilke kriterier legger dere til grunn, og hvilke metoder tar dere i bruk, ved beslutninger relatert til verdibasert innkjøp?

Helt til slutt, er det noe mer du har lyst til å tilføye?

Tusen takk for intervjuet, ha en god dag!
Oppfølgingsspørsmål:

- Kan du gi meg et eksempel?
- Kan du utdype denne ideen?
- Kan du forklare dette nærmere?
- Er det noe mer du ønsker å si om dette temaet?
INTERVIEW GUIDE – Healthcare provider

INTRODUKSJON AV INTERVJUER OG OPPGAVE

• Introduksjon av meg, Ably Medical og oppgaven
• Forklar formålet med intervjuet
• Opptak og transkribering av intervju
• Anonymitet, konfidensialitet og mulighet til å trekke seg

INTRODUKSJON AV INFORMANT

• Kan du fortelle kort hvem du er og hva du arbeider med?

INNKJØP AV MEDISINSK UTSTYR

• Hvilke krav setter dere til medisinsk utstyr og leverandører av slikt utstyr?
• Hvilke faktorer spiller inn i innkjøps beslutninger, og hvilke av disse er de mest avgjørende?
• Hvordan brukes resultater fra kliniske studier og økonomisk evalueringer av medisinsk utstyr i en behovsutredning og anskaffelsesprosess?
• Hva legger du i begrepet innovativt innkjøp, og hvilken betydning tror du innovativt innkjøp kan ha for helsesektoren?
• Hva legger du i begrepene «verdibasert helse» og «verdibasert innkjøp»?
• Hvilke kriterier legger dere til grunn, og hvilke metoder tar dere i bruk, ved beslutninger relatert til innovativt og verdibasert innkjøp?

ABLY BED:

• Hvilke forebyggende tiltak har dere for liggesår og hvor godt mener du disse fungerer?
• Hva tror du er sannsynligheten er for å få liggesår i løpet av et sykehusopphold?
• Hvilke krav stiller dere til pasientsenger?
• Kan du beskrive hvordan du ser for deg den optimale pasientsengen vil være?
• Ably Medical utvikler en smart pasientseng som er designet med langsgående, bevegelige fjærer og innebygde sensorer. Den er designet for å forbedre tre problemer relatert til pasientbehandling: fall, liggesår og belastning for helsepersonell. Hvilke egenskaper eller kriterier mener du er nødvendig med tanke på at sengen skal kunne ha en effekt disse problematicene?
• Jeg har gjort en kost-nytte analyse av sengen som et tiltak i tillegg til vanlig praksis for forebygging av liggesår, sammenlignet med vanlig praksis alene. Er dette noe som kan være av interesse for dere?
• Hvilke andre analyser eller informasjon vil være av interesse og ha en betydning for dere i en behovsutredning og beslutningsprosess?

Helt til slutt, er det noe mer du har lyst til å tilføye?

Tusen takk for intervjuet, ha en god dag!

**Oppfølgingsspørsmål:**

- Kan du gi meg et eksempel?
- Kan du utdype denne ideen?
- Kan du forklare dette nærmere?
- Er det noe mer du ønsker å si om dette temaet?
THE ABLY BED

The technology of the Ably Bed is patented, and a full description about the technology is available online, at the World Intellectual Property Organizations’ webpage. The various embodiments are illustrated in the figures below. The first figure (Fig. 1) shows the bed from a side angle. The next two (Fig. 2A and 2B) illustrates the springs of the bed that forms the very base. These springs are the central design to the prevention of HAPU, as it is they are intended to alter pressure points, by small movements in the springs. Figures 3A and 3B shows examples of how the supporting side parts are attached, and movable in different angles.

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2 A full description of the technology is available from: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018083566&recNum=1&office=&queryString=FP%3A%28ably+medical%29&prevFilter=&sortOption=Pub+Date+Desc&maxRec=12