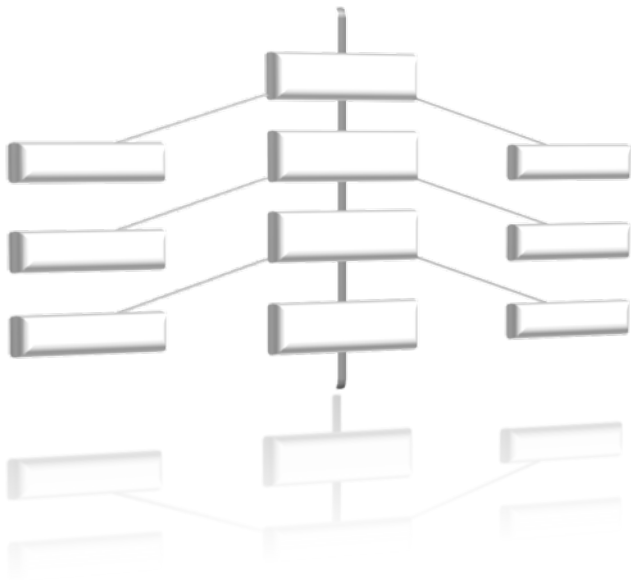
VALUE NETWORKS IN HEALTH CARE

THE CASE OF MANDIBULAR ADVANCEMENT DEVICES IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA

AUGUST 1ST 2013



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Preface & Acknowledgements

It was a pleasure to work on this project and gain insights about a complex medical disease as well as a thorough understanding of the value network concept. It was great to meet new and different people, including computer scientists and medical specialists. I enjoyed my time at Philips a lot and I would like to thank all my fellow interns and other colleagues for the great time.

Special appreciation to all interviewees for sharing their cooperation and providing me with their opinion and insights. Without them this research could not have been done.

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Abstract

Obstructive Sleep Apnea (OSA) is a chronic breathing disorder during sleep that is commonly treated with the Continuous Positive Airway Pressure (CPAP). Alternatively, Mandibular Advancement Devices (MAD) can provide an effective therapy. The OSA care path with the decision making actors has been analyzed and the key performance attributes of CPAP and MAD have been determined after 24 in-depth interviews with various care providers and a desk research on 82 sleep clinics in the Netherlands. This information was used to compose a value network, following the approach of Christensen and Rosenbloom (1995).

The value network allowed to derive strategic implications that incumbent CPAP firms should consider when entering the OSA treatment market with alternative treatments. Ten distinct actor groups were identified populating the value network. ENTs and pulmonologists were found to be especially important in therapy selection. Main performance attributes of the two treatments were found to be the clinical effectiveness and device comfort, which both have an effect on patient compliance and by that on the 'true effectiveness' of the treatment. MAD was found to perform better in terms of device comfort but performs less in clinical effectiveness. Therefore, MAD was not found to have a potential of taking over the severe OSA patients group. The tradeoff between device comfort and clinical effectiveness is better balanced in the mild OSA group. Because the MAD market in The Netherlands is already mature, the moderate OSA patient group is eligible for both treatment options, pinpointing the strategic battlefield of the two treatments. Options of combination-treatments should be investigated, especially for this patient population because synergies are expected to increase patient compliance and by that on the true effectiveness of these combinations.

The study has an explorative research design and concepts were developed throughout the research by using small research cycles. It contributed to the research on innovation in health care by applying a new approach of understanding the complex and multi-layered nature of treatment options for obstructive sleep apnea. This study links the value network approach to a care pathway analysis, making the roles of the various actors in clinical decision explicit, revealing the implications of incumbent firms that may want to enter this clinical field. A number of characteristics was identified when using value networks in health care. These include its multi-actor decision making, a-typical supplier-customer dynamics and health insurance regulation that pulls an emerging value network towards the established one.

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List of Abbreviations (LOA)

AASM	American Academy of Sleep Medicine
AHI	Apnea–Hypopnea Index
APAP	Auto-CPAP
BilevelPAP	Bi-level Positive Airway Pressure
CPAP	Continuous Positive Airway Pressure
ECG	Electrocardiogram
EDS	Excessive Daytime Sleepiness
EEG	Electroencephalogram
ENT	Ear, Nose and Throat (physician)
ESS	Epworth Sleepiness Scale
LAUP	Laser assisted UPPP
MAD	Mandibular Advancement Device
MRA	Mandibulair Repositie-Apparaat (NL; EN = MAD)
MSLT	Multiple Sleep Latency Test
Neur.	Neurologist
OA	Oral Appliance
ODI	Oxygen Desaturation Index
OMS	Oral and Maxillofacial Surgeon
OSA; (OSAS)	Obstructive Sleep Apnea / apnoea; (Obstructive Sleep Apnea Syndrome)
Pul.	Pulmonologist
PG	Polygraphy (sleep test)
PSG	Polysomnograpy (sleep test)
RDI	Respiratory Disturbance Index
RERA	Respiratory-Effort Related Arousals
UPPP	Uvulopalatopharyngoplasty (surgical intervention)

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1. INTRODUCTION

Obstructive Sleep Apnea (OSA) is a chronic sleep disorder caused by repetitive obstruction of the upper airway during sleep. As a result of this obstruction, the body makes transitions from deeper stages of sleep to shallower ones, resulting in too little deep sleep (Sands et al., 2010). OSA is associated with several forms of dysfunction including day time sleepiness, cognitive deficits, hypertension (Hla et al., 1994; Peppard and Young, 2000), strokes (Shahar and Witney, 2001) and an increased risk of motor vehicle accidents (George and Smiley, 1999). Patients suffering from OSA are found to have significantly impaired quality of life (Fornas et al., 1995) and undiagnosed OSA can be associated with higher rates of health-care use (Ronald et al., 1999). OSA's prevalence is 5.7% (men) and 2.8% (female) (Ram et al., 2010). Common OSA treatments include (1) Continuous Positive Airway Pressure (CPAP), (2) Oral Appliances (OA), (3) upper airway surgery and (4) lifestyle modification therapies (e.g. weight reduction and sleep position). CPAP is currently the most effective and standard treatment for moderate and severe OSA (Barnes et al., 2004; Giles et al., 2006). CPAP keeps the upper airway open during night by using positive air pressure. A type of OA, named Mandibular Advancement Device (MAD) is recently emerging in the treatment of OSA. MAD is a device that is worn in the mouth during night and puts the lower jaw forward, in order to create more space in the upper airway and reduce the number of obstructions. Despite that MAD treatment is less effective in a laboratory setting, it can offer a higher patient convenience and may equal CPAP in overall effectiveness, due to a higher patient compliance (Gagnadoux et al., 2009; Holley et al., 2011). CPAP is currently the standard OSA treatment, despite increasing evidence for MADs effectiveness (Almeida et al., 2005; Holley et al., 2011; Weinstock and Redline, 2012) and preference of MAD by patients over CPAP (Gagnadoux et al, 2009). The emerge of MAD technology can be a thread to parties that are commercially involved in CPAP treatment. These commercially involved parties form a value creating network. By introducing a value network approach, Christensen and Rosenbloom (1995) show how such a competition between an established and emerging technologies can be understood. A value network covers the playing field in which companies solve problems, react to competitors and strive for profit (Christensen, 1997). This approach allows for a strategic analysis of the multi-layered value creating business systems in which the competition takes place, including its suppliers and other commercially involved actors. Important in this value network approach is how the performance attributes system components are valued. Actors within this value network decide for one option or another, based on how they value specific performance attributes, i.e. characteristics of those options. The value network framework provides a promising analytic framework for the study of two competing medical treatment options and the consequences for commercially involved incumbents. The value network framework allows for a study of the competition between treatments and their context, as well as a the competition between devices within the same technology. The multi-layered approach helps in the identification of what system components compete on.

Christensen and Rosenbloom's (1994, 1995) notion of value networks has in previous literature been studied in relation to disruptive innovation (Christensen, 1997) and in relation to business models (Chesbrough and Rosenbloom, 2002; Sandström, 2010). Furthermore, the value network concept was used in the newspaper industry in order to understand the formation of new value networks of digital innovation (Åkesson, 2009).

Nevertheless, Sandström (2010) identifies the need for more focused research on value networks. "… *[the value network] theory had hardly been used in previous literature on entrant-incumbent dynamics*" (Sandström, 2010, p.8). Sandström (2010) argues for a better investigation of managerial implications of the theory and the study of incumbents in particular. This study takes the incumbent and company perspective into account in assessing the implications for an incumbent technology, being attacked by an emerging one. Another point on which this study strives for a better understanding of the value network approach, is to apply it in a complex health care situation. This typically includes complicated multi-actor decisions between patients, insurers and physicians. Being a disease that is treated multidisciplinary, OSA is a good example to study this multi-actor decision structure. Furthermore, this study adds the use of a care path analysis with the value network approach, which allows for the identification of important decision making actors and contributing to a framework of analyzing medical innovations. The work of Christensen et al. (2009) already touches upon the use of value networks in health care (pp.187-191). They discuss the complexity of value networks in the health care and the differences of health care compared to other sectors. In this thesis this is applied in a case study in order to assess the implications of using value networks in health care.

In order to study the case of CPAP and MAD treatment, the value network is in this research assessed as being the (1) *context* in which the competition between CPAP and MAD takes place, (2) *decision making actors* within the (business) system and (3) *key performance attributes* the technologies are valued on by the actors within this system. In the case of a medical treatment, such as CPAP and MAD, the *context* of the competition can be delineated by the 'care path' an OSA patient follows. A 'care path' includes the routes patients follow from a first diagnosis until a final treatment including all relevant actors the patient deals with, such as physicians, insurers and a patients' association. Second, although the care path contains a number of actor groups with their own valuation, not all actors play a role in deciding for a treatment. It is particularly important to identify the *decision making actors* in order to understand based on what the technologies are valued. Third, the decision making actors value technologies based on a set of characteristics that is referred to as performance attributes. The '*key performance attributes*' within a system level are a set of most valued performance attributes that form the measures along which a technology is valued by its customers. In the case of OSA treatment they can typically include the clinical effectiveness of the treatment, the patient's compliance and costs of the treatment. For this study, the Netherlands is chosen, because CPAP as well as MAD treatment is are both completely fully reimbursed as first line treatment in case of mild and moderate OSA, as opposed to other countries (Centrum Voor Slaapstoornissen, 2013). This research strives for the identification and assessment of the value network for MAD and CPAP treatment in the Netherlands and the strategic implications that can be derived from that for current CPAP producers in the Netherlands. This leads to the following main research question:

> *"What is the configuration of CPAP's and MAD's value network for the treatment of OSA in the Netherlands and which strategic implications for CPAP producers can be derived from this?"*

In order to answer the main question, the following four sub-questions are formulated:

- What does the Dutch *context* for OSA treatment look like; which *decision making actors* are in what way involved in the care path OSA patients can go through?
- How do the *decision making actors* within the OSA care pathway value the *performance attributes* of MAD and CPAP?

- What is the potential for MAD treatment to take over the current CPAP market?
- What are the strategic implications of this value network analysis for an incumbent firm that already sells CPAP devices in the treatment of OSA?

The value network application in this research results in an identification of the role of competition between two medical devices in the context of a care path analysis, including the valuation of performance attributes. This study contributes to the research on innovation in health care by applying a new approach of understanding the complex and multi-layered nature of competition between treatment options and medical devices. Furthermore, the study elaborates the understanding of a value network application, by applying it in a complex decision case and focusing on the implication of incumbent firms. On a strategic level, the study contributes to companies involved in OSA treatment by understanding the complex context within which the competition between devices for OSA treatment takes place. Also, it provides a direction on how to strategic positioning within the competition between MAD and CPAP. Another societal relevant aspect of this study is the need for an adequate OSA treatment. Analyzing the current value network around OSA can provide insights on how to improve the treatment processes in the Netherlands.

This thesis is structured as follows. Chapter two provides a more extended explanation of the disease profile of OSA, diagnosis methods and currently applied OSA treatment methods. Chapter three discusses the value network theory and its application within OSA treatment. Chapter 4 provides the research methodology, including a research design and the way of data collection and analysis. The research findings are presented in chapter five. In chapter six, the research findings are analyzed and the first three sub-questions are answered. Chapter seven provides the strategic implications of the research and an answer on the fourth sub-question. Subsequently, in chapter eight the conclusions are shown and the main research question is answered. Finally, in chapter nine the research outcomes and the use of the value network theory is discussed.

2. OSA: Disease Profile, Diagnosis and Treatment

Before the theoretic framework is discussed, this chapter provides an overview of the necessary background information to understand the disease profile, diagnosis and treatment of OSA, in order to understand the terminology and findings of this study.

2.1 OSA Disease Profile

Obstructive Sleep Apnea (OSA) is a chronic sleep disorder caused by repetitive obstruction of the upper airway during sleep. The upper airway can be blocked entirely (apnea), or partially, (hypopnea). The widely used definition of an apnea as defined by the American Academy of Sleep Medicine (AASM) is: "*the cessation of airflow of more than 10 seconds while asleep*" (AASM, 2007). This is accompanied by oxygen desaturation in the blood. The reduced O_2 saturation comes with an increase of the CO_2 saturation, resulting in a lower pH of the blood and finally a signal from the brain to make a transition to a swallower stage of sleep and breath. Such an event is called an 'arousal' and can be seen in the brain activity. A hypopnea, the situation in which the airway is partially blocked, can cause abnormally shallow breathing, also followed by a diminution in oxygen supply, resulting in an arousal. Hypopnea is defined as "*a recognizable, transient reduction but not a complete cessation of breathing of more than 10 sec in which a decrease >50% of the amplitude of a validated measure of breathing, or an amplitude reduction (<50%) that is associated with either an sO_2 decrease of ≥3% or an arousal*" (Barvaux, Aubert, & Rodenstein, 2000, p. 436). Respiratory related arousals including apneas, hypopneas and those that do not meet the official criteria of an apnea or hypopnea are categorized as 'respiratory-effort related arousals' (RERA).

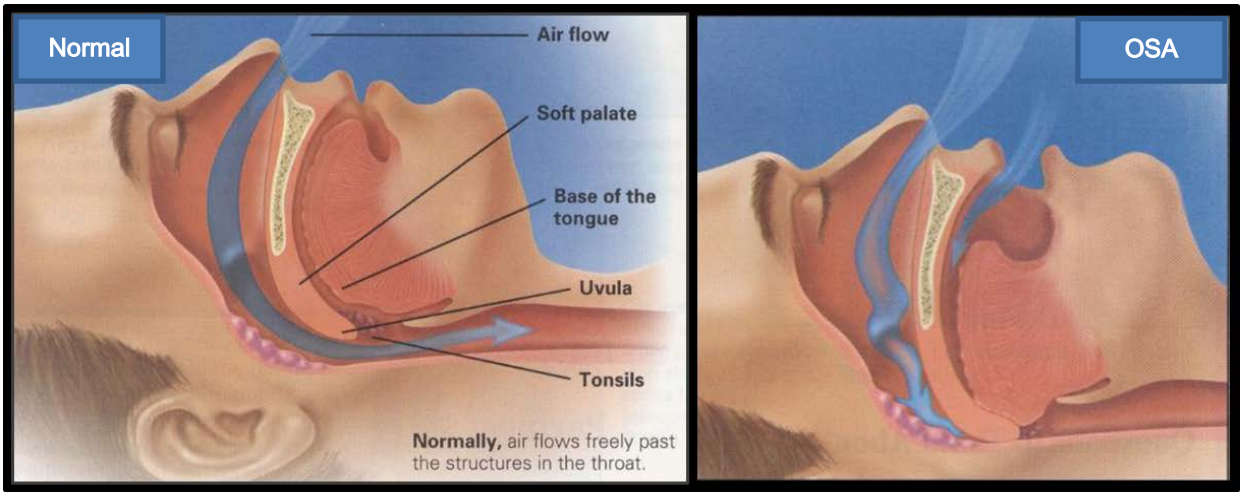

***Figure 2.1** – Cross section of the face during sleep, showing the difference between a normal person (left) and someone suffering from OSA (right). An Edit of (TMD Orthodontics and Sleep Center, 2013)*

Severity measures

In the first place, OSA severity is measured by the average number of apneas and hypopneas per hour of sleep, known as the Apnea–Hypopnea Index (AHI) (AASM, 2007). OSA patients are characterized by having ≥5 arousals per hour of sleep. An AHI of 5-15 is categorized as *mild*; 15-30 as *moderate;* and >30 as *severe* OSA. Alternatively, the 'Respiratory Disturbance Index' (RDI) is used instead of an AHI, taking into account all RERAs. In addition, the Oxygen Desaturation Index (ODI) and the patient's Excessive Daytime Sleepiness (EDS) is often taken into account as well. The latter is commonly measured on the Epworth

Sleepiness Scale (ESS) (Johns, 1991). Also a Multiple Sleep Latency Test (MSLT) or a Maintenance of Wakefulness Test (MWT) can be used to measure a patient's sleepiness (ibid). There can be a discrepancy between the AHI and ODI scores with the DTS. Following the Dutch Guideline for the treatment of OSA (Kwaliteitsinstituut voor de Gezondheidszorg CBO, 2009), the severity assessment should include all three types of measures. OSA prevalence studies show an occurrence between one and ten percent of the population (Barvaux et al., 2000). A recent study by Ram et al. (2010) on 6.139 American subjects shows a prevalence of 5.7% (men) and 2.8% (female).

Causes of Obstructions and Risk Factors

OSA is caused by a combination of factors. Factors most explaining the development of OSA are the anatomy, size, muscles and shape of the upper airway passage (Schellenberg et al., 2000). This manifests in the size and shape of the tongue (Friedman et al., 2004), combined with the size and shape of the tonsils, uvula, flaccid 'soft palate' parapharyngeal and lateral pharyngeal walls, the oropharynx (Ayappa and Rapoport, 2003), hypopharnix, epiglottis and the nasal passage (Sher, 2002). Furthermore, obesity increases the risk of having OSA, explaining the increasing prevalence of OSA (Ferguson et al., 1995; Herrendorf et al., 1996; Sampol and Munoz, 1998), since obese patients tend to have more tissue around the upper airway, belittling the airway passage and increasing the probability of collapsing tissue. OSA occurs more frequently in male patients than female patients (O'Connor et al., 2000) and there is a higher prevalence in the age of 50-69 compared to other ages (Ram et al, 2010). Besides, the sleep position can be of influence (Oksenberg et al., 1997; Richard et al., 2006). Within 55,9% patients the RDI dropped significantly when patients slept in a lateral position (i.e. on a side) as opposed to a supine position (i.e. on the back) (Richard et al., 2006). Additionally, the use of alcohol (Scanlan and Roebuck, 2000), sedatives (Eastwood et al., 2005; Chung et al., 2008) and smoking (Young et al., 2004) are all found to be related to the occurrence and severity of OSA (Punjabi, 2008). Although American men are in general more obese, OSA was more often diagnosed among people from South-East Asia, due to the anatomy of the face (Li, Kushida, & Powell, 2009; Punjabi, 2008; Ram et al., 2010).

Effects of OSA

During sleep, OSA is often associated with loud snoring including long stops, accompanied by gasping and chocking sounds. Other nocturnal effects include no or little deep sleep, witnessed apneas, insomnia, restless sleep, frequent arousals and tossing or turning during the night (Barvaux et al., 2000). Whereas day time effects may comprise EDS, morning headaches, dry or sore throat, short-time memory loss or other forms of impaired cognition, mood disorders and decreased libido (Barvaux et al., 2000; Engleman and Douglas, 2004). Regarding longer term effects, OSA has been associated with (1) strokes (Shahar and Witney, 2001) and is often related to (2) hypertension (Hla, Young, & Bidwell, 1994; Peppard & Young, 2000; Young, Peppard, & Gottlieb, 2002). Furthermore, OSA is found to affect several (3) cardiovascular functions including heart failure (Bradley, 1992), vascular injury, acceleration of atherosclerosis due to episodic hypoxemia (Gainer, 1987), chronic sympathetic hyperactivity (Narkiewicz and Borne, 1998), elevated pulmonary blood pressure and increased risk on hypertrophy (Guidry et al., 2001). Furthermore, OSA is related to (4) diabetes type 2 (Foster et al., 2009). Additionally, OSA is frequently reported to be related to an significantly (up to 15 times) increased chance of (5) motor vehicle crashes (Young et al., 1997; Teran-Santos, 1999; Ellen et al., 2006) or (6) other occupational accidents (Horstmann et al., 2000). Finally, OSA is stated to influence the (7) menopause and (8) negatively influences pregnancy (Young et al., 2002).

2.2 OSA Diagnosis

OSA diagnosis in the Netherlands consists of a sleep study, day time sleepiness test and anamnesis, i.e. medical history and physical examination. The sleep study is a major part of the diagnosis, resulting in an AHI score. Two types of sleep studies can be distinguished. Polysomnography (PSG) includes measures of the respiratory inductance plethysmography, respiratory airflow measures, respiratory effort measures, electroencephalogram (EEG), electrocardiogram (ECG), electrooculogram, electromyogram (i.e. limb movement), peripheral pulse oxymetry and oxygen saturation. PSG can be performed in a hospital (clinical or laboratory-based) or at home (ambulant). Nocturnal, laboratory-based PSG is the most common form and can optionally be filmed and monitored over night (Kushida et al., 2005; Kushida, 2007). A simpler sleep test is a polygraphy (PG), alternatively named "cardio-respiratory monitoring". PG does not take brain activity into account. Like PSGs, PGs are performed laboratory-based and ambulant. Yet, a general problem regarding P(S)G, is night-to-night variation in patients' AHI / RDI and ODI (Fietze et al., 2004). A comprehensive diagnosis should therefore include several over night studies. However, this is rather uncommon because of the high costs of a single P(S)G study. A further elaboration on the different types of P(S)G, is given in Kushida et al. (2005). For a more extended overview and criteria, see (Collop et al., 2007).

In order to detect the place(s) of obstruction, P(S)G is often followed – or sometimes preceded – by an inspection of the mouth, throat and nose, performed by an Ear, Nose and Throat physician (ENT). This is most commonly done during a sleep-endoscopy, i.e. the examination of the obstruction areas during a short medicine induced nap. As a part of the sleep-endoscopy, an ENT can perform a 'chin-lift' in order to predict the effectiveness of MAD devices. Less commonly used are CT-scans, fluoroscopy and MRI-scans.

2.3 OSA Treatment

The aim of OSA treatment is reduction and ultimately elimination of the patient's complaints, improvement in parameters measured during P(S)G (e.g. AHI) and reduction in patient's long term risks. OSA treatments can be categorized in treatments using Positive Airway Pressure (PAP) devices Oral Appliances (OA) and other treatments including surgical interventions, life style therapy and medication treatment. The different methods are presented below. Because of the focus of this thesis, (C)PAP and MAD are discussed more extensively. This focus is chosen because CPAP is the current standard treatment and MAD is the second largest and fastest emerging alternative.

(Continuous) Positive Airway Pressure, (C)PAP

PAP devices blow air into the upper airway. In doing so, they increase the air presure within the upper airway, reducing iets probability of collaps. Simular to the inflation of a tire, the airway remains open. This is shown in figure 2.2, based on (Sullivan et al., 1981), who first published about CPAP devices.

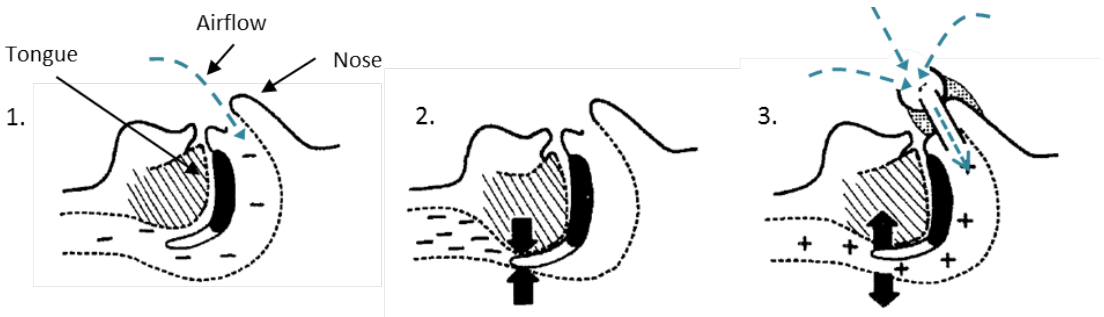

Figure 2.2 *– The working of CPAP; 1. A normal patient during sleep; 2. An OSA patient during an apnea; 3. An OSA patient wearing CPAP. The air pressure keeps the patient's airway open. An edit of: (Sullivan et al., 1981, p. 863)*

PAP comes in several forms including continuous PAP (CPAP), Bilevel-PAP and Automatic adjusting PAP (APAP). CPAP works with a continuous air pressure, whereas in APAP the pressure is continuously adjusted to the needed pressure for keeping the airway open. Using Bilevel-PAP the inspiration and expiration pressure can individually be adjusted. As can be seen in picture 2.3, a CPAP device contains out of a mask, hose and a pressure machine. Masks come in nasal and full face masks. For convenience reasons, incoming air can optionally be warmed or moistened. CPAP - the most prevalent of the three - is considered as the golden standard for the treatment of moderate and severe OSA (Giles et al., 2006). In a review article, Gay, Weaver, Loube, & Iber (2000) show that CPAP has been proven as an effective method in decreasing the AHI in all of the 11 clinical studies that are taken into account. Despite its high effectiveness in AHI reduction, the effectiveness of CPAP is often limited by suboptimal compliance due to poor patient acceptance and tolerance (Weaver and Grunstein, 2008). Although APAP and Bilevel-PAP may in some cases increase convenience, it does not improve compliance (ibid.). For each patient, the pressure differs. Titration, the process of setting the pressure (in cmH_2O) is generally performed by a pulmonary specialist or clinical neurophysiologist. Pressure contains typically 5-13 cmH_2O. Patients do generally not tolerate a pressure of ≥15cmH_2O (Marrone and Salvaggio, 2008).

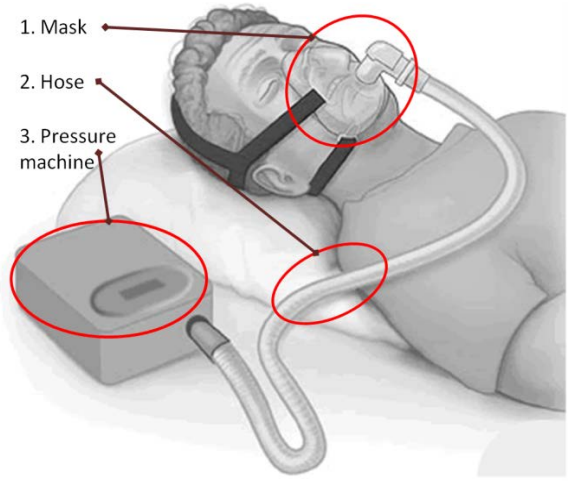

Figure 2.3 *– CPAP during sleep (using a full-face mask) An edit of (Healthwise 2013)*

Oral Appliances (OA), including MAD

Oral appliances work by putting the lower jaw to the front. This increases space behind the tongue in the upper airway and by this prevents obstructions. The most commonly prescribed type of OA is a Mandibular Advancement Device (MAD). This device comes in many forms that can be categorized in three types: The first is a customized (alternatively called 'tailored', 'custom-made' or 'adjustable') MAD and second the pre-fab *boil & bite* alternate. The third category, *passive MADs* contains MADs that do not protrude the mandibular. The customized MAD have been showed effective in AHI reduction, retention and overall effectiveness, whereas the *boil and bite* (Vanderveken et al., 2008) and the passive MAD (Lim et al., 2009) have not. In this report, MAD refers to the more effective adjustable MAD types. Other forms of oral appliances include "tongue-retaining devices" (TRD) - to secure the tongue in a forward position - "Mouth shields" and "soft palate-lifting devices" (Hoffstein, 2007). However, all of these options have not yet been proven effective in AHI reduction or the overall effectiveness in the treatment of OSA as compared to customized MAD (Schönhofer et al., 1997; Barthlen et al., 2000). In addition, the patient's compliance and acceptance of TRD devices is low (Schönhofer et al., 1997). The rationale behind the efficacy of MADs is the advancement of the mandible (lower jaw), in order to enlarge the pass-through of the upper airway and, as a result, preventing the upper airway to collapse during sleep (Clark et al., 1993). Mono-block MADs comprise out of one piece of material, as opposed to duo- /dual- /twin-blocks that exist out of two parts; one for the

upper and one for the lower jaw. Furthermore, MADs can be adjustable or not. Besides they can have a soft or a hard layer inside. Figure 2.4 shows an adjustable twin-block MAD. The small yellow arrow shows the adjustment part. The blue arrows show the direction of advancement. The distance the mandible is advanced is called the 'protrusion'. The titration is the process in which the protrusion is set. This may take a couple of tries before the right balance is found between discomfort and effectiveness. MADs are increasingly prescribed for the treatment of mild and moderate OSA (Kushida et al., 2005; Kwaliteitsinstituut voor de Gezondheidszorg CBO, 2009). MAD was first reported in literature in the year 1984 by Meier-Kwert and colleagues, three years after the introduction of CPAP who subsequently they reported its effectiveness in 1986, using their one-piece forward MAD (Clark, Arand, Chung, & Tong, 1993; Clark et al., 1993; Kloß, Meier-Ewert, & Schäfer, 1986). However, approximately one third of the OSA patient's are deemed not eligible for MAD, considering limitations in the condition of patient's teeth (Petit et al., 2002). Such restrictions include periodontal disease, poor condition of the teeth, temporomandibular joint disorders and movement limitations of the mandible. Figure 2.5 shows a patient wearing a MAD (right picture) picture, as opposed to the same patient not wearing a MAD (left picture). It is seen that a MAD increases the space in the upper airway.

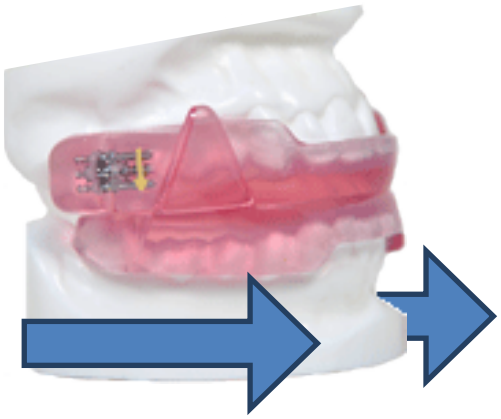

Figure 2.4 *– Mandibular Advancement Device (Dental Prosthetic Services, 2013)*

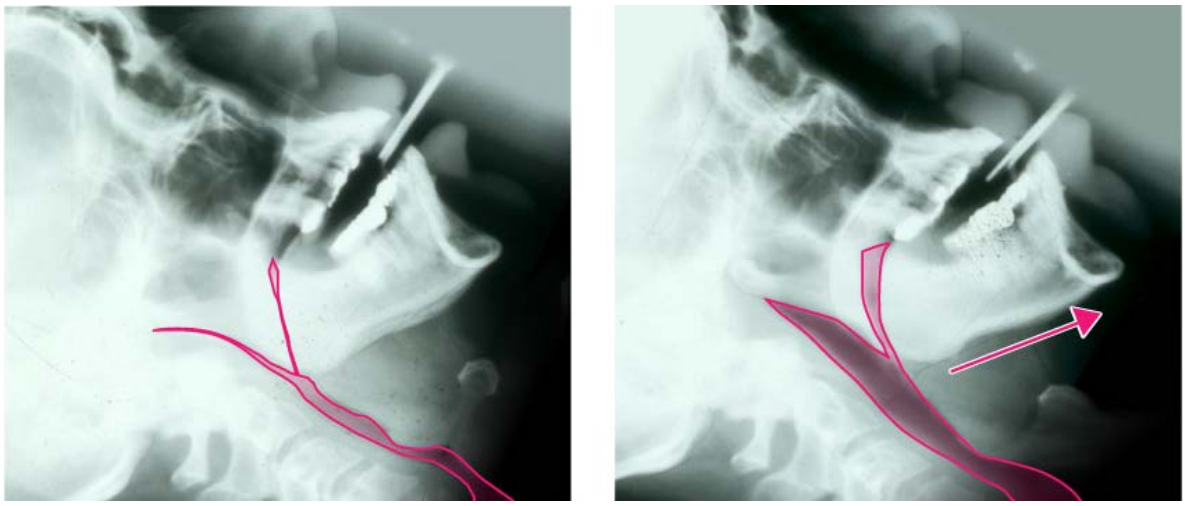

Figure 2.5 *– OSA patient without (left picture) and with (right picture) Mandibular Advancement Device (MAD). The upper airway is marked purple. It is seen that a MAD increases the space in the upper airway (right picture).* (Easy Comfort MRA 2013)

Other OSA Treatment Strategies

Several types of *surgical interventions* can be applied in the treatment of OSA (Sher, 2002). First, by removing tissue from the mouth and upper airway, the air passage enlarges. Uvulopalatopharyngoplasty (UPPP) is the commonly applied surgical method creating more space in the upper airway (Kwaliteitsinstituut voor de Gezondheidszorg CBO, 2009). Ablation interventions also include laser assisted and radiofrequency-

based (LAUP) in order to increase the rigidness of the tissue and therefore reducing the probability of collaps. Second, repositioning interventions include skeletal modifications such as mandibular advancement and soft tissue repositioning. A third option are *implants* that suspend and stabilize the tongue. Fourth, a *nervus hypoglottis stimulation device* can be implanted and attached to the tongue nerve. In case an apnea is detected, the tong will stretch. Finally, as a last resort for very severe patients, the 'tracheotomy' intervention entirely by-passes the upper-airway. A complete and more extensive overview of surgical interventions is provided in Sher, (2002).

Lifestyle modification therapies are in case of mild OSA often suggested as a first OSA treatment. Conservative therapy may include weight reduction programs, reduction in (evening) alcohol consumption, smoking cessation, avoidance of sedative medication and position therapy in case of position dependent OSA (Kushida, 2007). *Position training devices* can be used for positional related OSA. This type of device trains patients to sleep in a lateral position as opposed to a supine position. Several *medication treatments* are suggested in the treatment of OSA. These include medications that affect airway tonus during sleep, stimulate the respiratory, vasoactive drugs and local medication treatments in the upper airway. Nonetheless, a literature overview by Smith, Lasserson, & Wright, (2006) shows that none of the medication treatments have yet been proven effective in controlled randomized studies, as compared to other available options. Finally, a *nasal stent* is a tube that a patient can insert in his upper airway by putting it through the nose, which is described in (Satoh et al., 2013). Being in an experimental phase of development, no articles could be found on the effectiveness and compliance of nasal stents.

Specialists Involved in OSA Diagnosis and Treatment

Several specialists are involved in OSA diagnosis and treatment. Regarding the Dutch situation, after a General Practitioner (GP) refers a patients to a sleep clinic, an Ear, Nose and Throat physician (ENT) and the pulmonologist are the most common medical specialists to visit. OSA nurses are involved in the process, helping with the intake, sleep tests and process management. Patients can be sent to a neurologist in case a combination with other sleep disorders are suspected. In case MAD treatment is chosen, other specialists come into play. These include an Oral and Maxillofacial Surgeon (OMS), a (dentist) gnathologist, orthodontist or regular dentist. Gnathology is a specialism in the field of dentistry; the study of the masticatory system (i.e. chewing system) including its physiology and functional disturbances. CPAP is most often titrated by a pulmonologist or pulmonary nurse, but can also be titrated by a clinical neurophysiologist. Due to OSA's comorbidity other specialists are involved as well, including dieticians, therapists and cardiologists.

Now that the clinical background of the disease including its diagnosis and treatment options and involved specialisms is discussed, the next chapter provides an elaboration on the theoretical framework that is used to analyze the research problem.

3. THEORETICAL FRAMEWORK

This chapter discusses the value network concept and its application in CPAP and MAD treatment.

3.1 VALUE NETWORKS

A (value) network approach allows for an understanding of (commercial) value creation within the multidirectional and complex nature of the health care sector, as opposed to more linear approaches (Allee, 2000; Basole and Rouse, 2008). Value networks include sets of actors and value creating interactions needed to achieve value of an innovation (Allee, 2008). The value network approach of Christensen & Rosenbloom (1995) add the notion of a multi-layered disentanglement of into sub-systems that exist around one product. Subsystems are than valued on performance attributes by important actors that decide to choose one option or another. The disentanglement into sub-systems allows for understanding the role of a emerging technology by understanding the context in which competition takes place at each of the system levels. The identification of (decision making) actors makes clear how they choose for a treatment (or device) based on their valuation of performance attributes. The value network approach provides the ability to – from an innovation study perspective – understand the potential of technological trajectories replace existing ones and – from a company perspective - derive strategic implications for how to position itself between an established and emerging technology.

The concept of a value network[1] was introduced by Rosenbloom and Christensen (1994) and Christensen and Rosenbloom (1995) and elaborated on by Christensen (1997). Next to the magnitude of technological improvement or the organizational difficulties to adopt new technologies, companies are nested in a commercial system that drives their technological developments towards incremental innovation. Christensen (1997) provides a definition of such a commercial system as a 'value network', being; "*The context within which a firm identifies and responds to customer needs, solves problems, reacts to competitors and strives for profit*" (p.36). The value network can be seen as a complex system of suppliers and customers involved in a product. The end-product acts as a component within this complex system. It can however also be viewed as a system in itself, including components the product is built of and their architecture. Hence, the value network shows a stratification; components within the value network are hierarchically nested in a set of sub-systems. Likewise, when zooming in, each component in the system can be seen as an architected system of itself and complex architected systems act as a component in higher-order levels of the system. Next to a set of components and a system architecture, each level of the network includes a set of suppliers and a set of performance attributes that are valued most by its customers. Suppliers of components in one system level serve higher-order system suppliers as their customers. As a result, the value network implies a nested network of producers and markets through which the tradable architected components at each level are made. Performance attributes are product characteristics based on which a product is valued. Understanding the relative importance of performance attributes to deciding actors in a system level allows for an

[1] 'Value networks' in this research refers to Christensen and Rosenbloom's (1995) interpretation of the concept. *Value network'* in the academic literature is also used in a broader sense of being a web of actors and their value creating interactions in all sorts of forms. For examples, see (Allee, 2000; Peppard and Rylander, 2006; Basole and Rouse, 2008; Heikkinen and Luukkainen, 2010)

understanding of the aspects of products on which competition within this system level is based. The 'key performance attributes' within a system level is a set of most valued performance attributes that form the measures along which a technology is valued by customers and optimized by suppliers.

Following Christensen's (1997) example, one of the components of the system 'personal computer' is a 'disk drive'. When zooming in on a next level, a disk drive in itself can again be seen as an architecture system, built out of components as, 'read-write heads', 'motor' and 'power dissipation' each having their own suppliers and performance attributes on which higher-level suppliers value the components. Figure 3.1 provides an example of such a value network within the disk-drive industry as presented by Christensen & Rosenbloom (1995). This figure can be seen as a cross section of a value network through different levels. The suppliers of the components are show left from the middle blocks. Right of the middle blocks are the key performance attributes of which the components are valued by the higher-level suppliers, i.e. its customers.

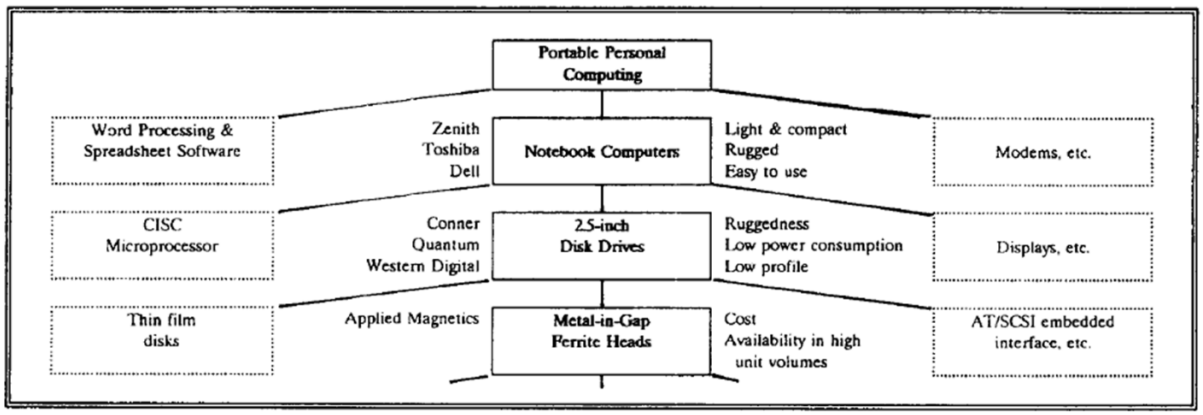

Figure 3.1 *– Example of a value network for the disk drive industry (Christensen & Rosenbloom, 1995, p.239)*

3.2 VALUE NETWORKS AND DISRUPTION

Once nested in a certain system structure, the architecture of a value network is hard to change and lock-in effects appear. This is caused by the perception of established firms in the value network, that consequently drives the allocation of resources towards improvements of the system's *components*, not the system's *architecture*. This makes it difficult for a new technology to 'comply' with the existing architecture, when valued along the measures of value within the existing value network (Christensen & Rosenbloom, 1995). When valued along the same value measures of the existing technology, the new technology may be inferior, but when valued along a different set of values, the new technology may have advantages. In the latter case, a new value network with a different architecture can be created around a redefinition of value, which will exist next to the established value network (Christensen, 1997). Furthermore, the rate of improvement in product performance by the established technology may exceed the rate of improvement demanded in established markets. When this mismatch occurs, the established value network can be attacked by the new emerging value network, because the new emerging technology can offer the demanded product performance for a lower price. In this case the new value network has the potential to disrupt the existing value network. This is shown in figure 3.2.

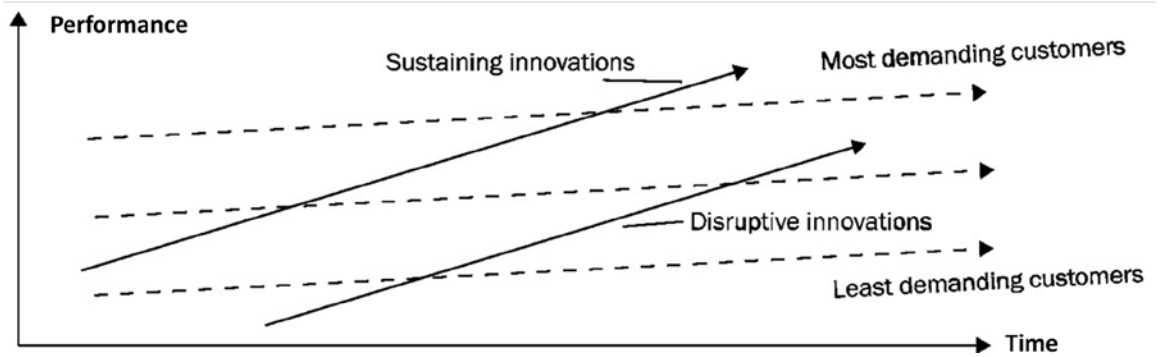

***Figure 3.2** – The disruption of an sustaining innovation, based on (Christensen, 1997, p xvi)*

3.3 Value Networks within OSA Treatment

Several differences regarding the application of the value network theory in the case of MAD and CPAP and the original Christensen & Rosenbloom (1995) article are discussed in the next section. Thereafter, the model with the system delineations for CPAP and MAD treatment is presented.

Notably, Christensen and Rosenbloom (1995) use the mapping of a value network as an argument why attackers have an advantage over established market players. Christensen et al., 2009) touche upon the use of value networks in health care (pp.187-191). They noted the complexity of the health care sector and imply the great complexity of its value networks, which may be simpler in other sectors. Additionally, they discuss how consumers play a different role. The decisions for a patient's treatment are often made – or heavily influenced - by independent, certified physicians and largely paid for by insurance companies and governments. Additionally, patients can go through different routes from a first diagnosis until a final treatment, whereas e.g. computer parts are always assembled in the same sequence towards higher-level systems. Moreover, what is sold in the CPAP and MAD value network is not the patients themselves, but an increase in their health. These differences are taken into account when delineating the system levels in the next paragraphs.

The use of different system levels is inherent to the use of the value network approach and helps in the assessment of decision making actors and key performance attributes in each sub-level of the system. This results in an understanding of the system's configuration, how an OSA treatment is chosen and the role of companies within these treatments. The next paragraphs provide the delineation of the system levels for CPAP's and MAD's value network that act in this research as the heuristic tool, guiding the exploration in the empirical data in order to identify decision making actors and key performance attributes. The choice for the system levels is based on criteria that are derived from the way Christensen & Rosenbloom (1995) present the value network of a disk drive. First, levels are a system that are a component in the higher-order level systems. Second, the levels have a set of suppliers that serve the higher-order level suppliers. Third, each level has another set of performance attributes where the system is valued by its customers that may or may not be related to higher-level system performance attributes.

As Christensen & Rosenbloom (1995) state, the end product – in this case an OSA treatment - may be viewed as a component within a system, relating to other components within an architecture, which shows the

context in which the product is used. Thus, a first system-level provides the context in which OSA treatment takes place. This '*overall OSA'* level is delineated by the OSA 'care path'. A care path includes the components diagnosis, OSA treatments, scientific research, the patients' association and relevant actors including GPs and physicians. This system level demarcation was chosen because it is delineated by where patients go and thus includes the important components regarding OSA diagnosis (of patients) and treatment (of patients). Correspondingly with Christensen & Rosenbloom's (1995) value network, this system level has no suppliers or performance attributes, but rather provides the context in which the product – or in this case treatment - is situated.

Second, when zooming in on the component *OSA 'treatment options'*, a new system occurs containing a subset of all parties involved in the overall system that are directly relevant for the direct treatment of OSA. This includes a process of deciding for a specific treatment. Sleep clinics can be seen as the supplier for this process. It is this *treatment options* system level however, where the conceptual difference with a merely technology related value network becomes apparent. A sleep clinic does not sell a patient to a pulmonologist. Rather, the sleep clinic gets reimbursement money to enable a physician to make an informed decision for which treatment to choose and subsequently apply or perform this treatment. Also, components (physicians and the different treatment options) do not show a typical relation in this level, because the different treatment options do not interact as system components within a nested architecture. However, the *treatment options level,* is an important analytical level in understanding the key performance attributes on which the treatment options are valued. Before the acquisition of empirical data, a first limited set of key performance attributes was identified from the academic literature and used as sensitizing concepts in exploring expert interviews. These are the *clinical effectiveness* since it is widely used to compare treatments (e.g. Gagnadoux et al., 2009), comfort since this was stated to be an advantage of MAD therapy (e.g. Lettieri and Paolino, 2011) and the compliance, that was found to be important in longer term effectiveness studies (e.g. Waldhorn et al., 1990).

Third, the two components in the treatment options level that are under investigation are 'CPAP treatment' and 'MAD treatment'. Being components in a higher-order-level, treatments can again be seen as a system composed of the process components 'titration process', 'follow ups', 'guidance and coaching' and the devices itself. Since CPAP and MAD treatment are two different systems, they need to be analyzed separately. The 'suppliers' in the treatment level can typically be pulmonary physicians (CPAP), or the dentist and OMS (MAD) treatment level. They are hired the higher-system-level suppliers, being the sleep clinics. Suppliers in this level have no typical supplier-customer relation. Except for special and complex cases, the sleep clinics – represented by its own specialist - tend to choose their own personnel to treat a patient. It is thus not likely that after a diagnosis a specialist sends the patients to other sleep clinics, because their treatment process is differently organized. This means that the key performance attributes in this level conceptually act differently; they are important aspects of the treatment, more that play a determinative role in which specialists are chosen to perform a treatment.

A fourth level, the '*device level*', zooms into the devices itself being a system. Components in the CPAP device level are the masks, the pressure machine and the hoses. The suppliers are companies that provide CPAP devices. The MAD device level includes the components frame, adjustability gear and an inside layer. Suppliers provide MAD devices. In this system level, the suppliers clearly serve the higher-system-level suppliers; The CPAP device is bought by the pulmonologist (although paid by the health insurance) and the MAD device is bought by the dentist or OMS (idem). Performance attributes in the device level concern the competition among different devices itself, not among treatment options.

The delineation of the OSA value network and its system levels is graphically presented in figure 3.3. The figure is based on the value network model as presented in figure 3.1. The lower-ordered levels are components in the higher-order levels and therefore represented with a smaller size in the figure. The treatment level and the device level differ for CPAP and MAD and are split in the analysis. On the left side the system components are shown. The framework as graphically presented in figure 3.3 thus forms the heuristic tool for guiding the exploration process in identifying decision making actors and key performance attributes in the empirical data.

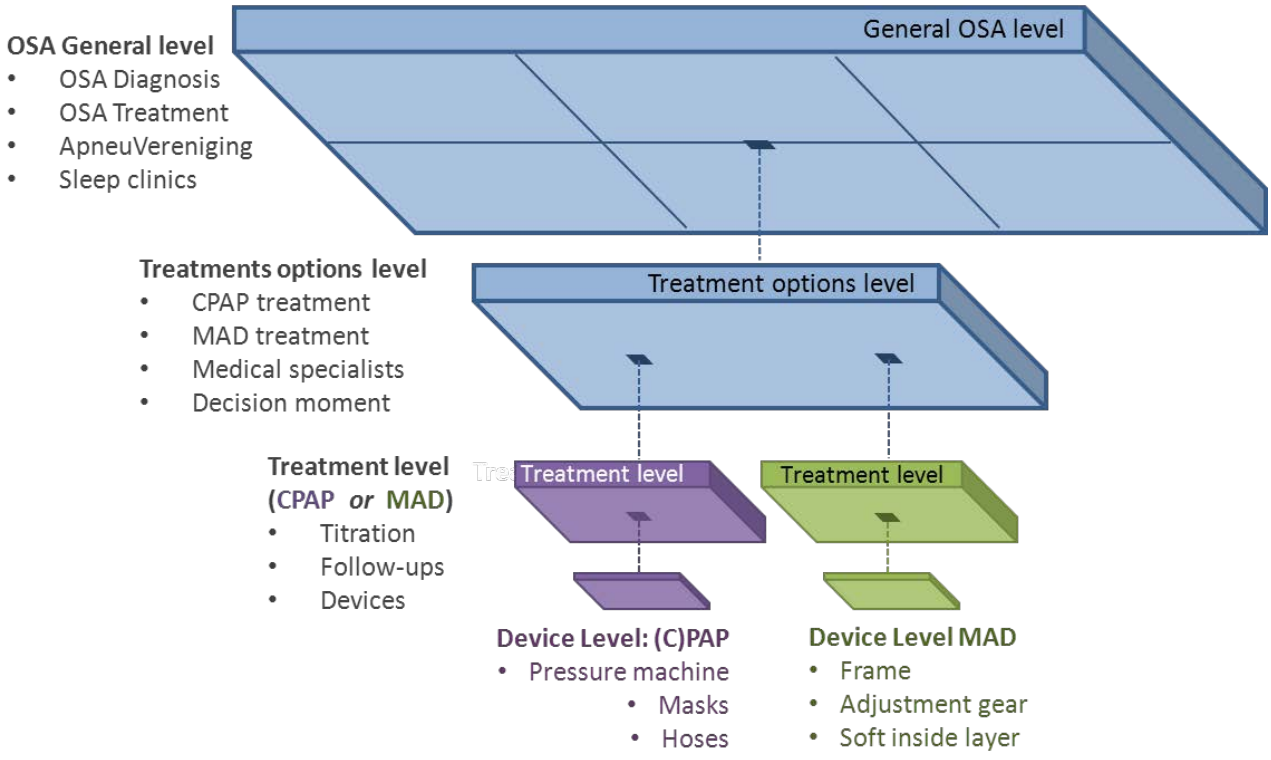

Figure 3.3 *– Representation of the components within the CPAP and MAD value network.* (Blue = shared | Purple = CPAP | Green = MAD)

4. METHODOLOGY

This chapter illustrates the research method by showing the research design, case selection, method of data gathering and analysis. Since the quality of qualitative research lies in the process (Eisenhardt, 1989), the process of data sampling and analysis is extensively reported and discussed.

4.1 RESEARCH DESIGN

This research strives to identify and assess the CPAP and MAD value network configuration in the Netherlands and derive strategic implications from this. The identification of how performance attributes are valued is best supported by an exploratory research design. Within the delineation of the system levels as described in the theory chapter, key performance attributes were not operationalized beforehand, but developed though small research cycles with explorative interviews with leading expert.

The actor identification within the value network - in this case delineated by the OSA care path - was done by desk research on sleep clinics in the Netherlands. This analysis provided relevant actors in the system, which largely comprised physicians in various specialisms. Additionally, the five explorative in-depth interviews with experts in the field of OSA treatment could verify the results from the desk top study. Together with the expert interviews and the desk research, this resulted in a more complete overview of the OSA care path in the Netherlands. To identify the values, a qualitative research approach was chosen, since this allows for the identification of values and suits revealing the explorative character of the research study. The Netherlands is chosen because CPAP as well as MAD treatment are both fully reimbursed as first line treatment for mild and moderate OSA, as opposed to other countries (Centrum Voor Slaapstoornissen, 2013).

4.2 DATA SAMPLE

A 'purposive sampling' strategy (Patton, 2002) was applied for the selection of five leading experts in the field of OSA treatment. Among the experts were three ENT's, a dentist gnathologist and representative of the patients' association. Four of them are leading researchers in the field of OSA, three hold a doctorate degree in OSA treatment and three have later in interviews been recalled as leading OSA experts. Three experts responded positively on an interview request and helped in contacting the two other experts.

Based on the results of these exploratory expert interviews, subsequently a broader sample of interviewees was selected that represented actors in the OSA treatment system. The explorative expert interviews showed that insurers and patients play a role, but the decision for one treatment or another is made by medical specialists. The medical specialists are therefore an important group for identifying key performance attributes. The number of interviewees was based on their importance within the OSA care path, as identified by the expert interviews in combination with the desk research. Table 4.1 provides an overview of the respondents. ENTs, Pulmonologists and OSA nurses were selected in relative high numbers because they are all important actors in the treatment options level all participating in treatment decisions. The way these three actors value performance attributes is particularly important in understanding the choice for one treatment or another. GPs and the patients' association are part of the overall OSA level and were to provide information on the OSA care path. Three dentists, one MAD company and two OMSs were selected in order

to identify performance attributes within the MAD device level and treatment level. In order to find key performance attributes within the CPAP device level a number of stakeholders within a CPAP company were to be interviewed, but this led to no response. However, performance attributes in the CPAP device level could largely be covered by the pulmonologists, OSA nurses and neurologists interviews. These also provided important performance attributes at the CPAP treatment level. Because of the multidisciplinary character of OSA treatment, one focus group interview was conducted with five specialists. It can be seen that ten out of the eleven actor groups have been interviewed, due to no response within the CPAP company. The multidisciplinary team was not taken into account as an actor, but comprised interviewees from the other actor groups.

Within the boundaries of this purposive sample, the interviewees were selected by calling the 82 sleep clinics in a random order. After 50 sleep clinics were approached, the required number of respondents was reached. Based on their market share, the three largest MAD producers were contacted, of which one - the largest, representing 60 to 70% of the market - agreed for an interview. The Netherlands has one OSA patients' organization, which was represented by a board member.

Table 4.1 *– Overview of respondents within actor groups and the levels of the value network covered by the interviews . *Number of respondents.*

Actor groups	Number of Interviews	General OSA level	Treatment opt. level	Treatment level CPAP	Treatment level MAD	Device level CPAP	Device level MAD
ENT	5	X	X		X		X
Pulmonologist	4	X	X	X		X	
OSA nurse	4		X	X	X	X	X
Dentist	3				X		X
GP	2	X					
Neurologist	1		X	X			
OMS	1				X		X
Somnologist	1	X	X			X	
Patients' association	1	X	X	X	X		
MRA producer	1						X
Focus group	1 (5*)	X	X	X	X		
CPAP company	*0 (3-5 planned)*					X	
Total	24 (29*)						

The sample includes a wide range of types of clinics, varying from peripheral clinics and third line distinct sleep clinics to academic hospitals in the Netherlands. The sample of sleep clinics is located all over the Netherlands, including Alkmaar, Amsterdam, Assen, Baarn, Geldrop, Groningen, Utrecht, Rotterdam and Zwolle. Furthermore, a broad range is also seen in the interviewed type of dentists, since the sample includes a regular dentist who almost never performs an MAD therapy, a performing dentist gnathologist and a researcher dentist gnathologist. The interviewed GPs and dentists were randomly selected and located in different cities in the Netherlands that were close to cities where other specialist interviews were conducted that day. The dentists and GPs are located in Amsterdam (2x), Maarsen, Heerhugowaard and Utrecht.

The desk research was conducted by using the websites of 82 sleep clinics in the Netherlands which were identified in a report by the Apneuvereniging (2011). Using the search engine 'Google' no other sleep clinics were found next to the list of the Apneuvereniging (2011). Thereafter, data was acquired from the sleep clinics' websites regarding the number of OSA patients a year, the specialists responsible for the intake, the presence of different specialists and if MAD treatment was performed. This was complemented by information on the website of the Dutch Apneuvereniging (http://www.apneuvereniging.nl)), the OSA patient organization in The Netherlands, in the period March 2013. In case of conflicting information, the sleep clinics' websites were used, since this was an original source. One clinic was excluded from the analysis, since no information could be acquired.

4. 3 DATA ACQUISITION

Semi-structured, in-depth interviews were chosen for all interviews, for their feasibility and ability to provide detailed and rich content. Furthermore, they allowed more than other research methods for identification of underlying motives and values, which made them particularly useful in this research. Because, the answers to the questions could be followed up by new questions, it was useful in the identification of values. The expert interviews were more open compared to other stakeholder interviews. The expert interviews contained only six open questions, in order to reduce any guidance in their answers or narrowing of the conversation. The questions were based on the identification of key performance attributes in the different levels of the value network model, that served as an heuristic tool. Once a first set of values was identified based on the five expert interview transcripts, the subsequent interviews allowed for a more structured questionnaire. The main questionnaire and the open expert interview questions are shown in Appendix C. The questionnaire was tailored for each stakeholder. The tailored questionnaires are available on request.

4.4 DATA ANALYSIS

The writings of Corbin and Strauss (1990); Goulding (2002); Patton (2002); Flick (2009) and Richards (2009) provided the guidelines on which the analysis is based. In spite of their somewhat different approaches, they all emphasize the process of developing concepts through induction, where one should abstract away from the data and then test the concept and relations to the data (deduction) by using small research cycles. Eight empirical cycles were used in the analysis. A first set of values was identified from the academic literature and subsequently used as sensitizing concepts. These contained the 'effectiveness', 'comfort' and 'compliance' of a treatment. After a first expert interview was conducted, a first empirical cycle of global coding was performed on its transcript. Important parts of the text that concerned a 'value' were highlighted and put in a table in Microsoft Excel. After a refinement in the questionnaire, the other four expert interviews were conducted. Again, a global coding strategy was conducted on the transcripts and put together in the same table in Microsoft Excel. This resulted in a 43 page document including 79 different codes, of which an example page is presented in step 2, Appendix B. As a next analytical step the 79 codes were grouped into 26 more general codes (Appendix B, step 2). Next, in order to abstract away from the data, a categorization of the 26 codes was put into the value network model. Thereafter, this set of general and categorized codes was refined by again going through the five interview transcripts, in order to check if the codes captured all the important statements and concepts from the data. This refined set of categorized codes was

operationalized in order to create the stakeholder questionnaires that are presented in appendix C. Each code was asked about in one, two or three open questions. For example the code 'compliance' was asked for as "*What is the role of compliance within an OSA treatment*?" An overview is provided in Appendix B, step 4. After three stakeholder interviews were conducted, a coding scheme was created based on the categorization of codes from the expert interviews. The coding scheme simultaneously developed with the conduction of the other stakeholder interviews and likewise new codes emerged. This resulted in ten Excel files, one for each of the ten stakeholder groups as presented in table 4.1. Each file contained five worksheets, one for each part of the value model. Next, the codes were regrouped, refined and categorized were possible, resulting in four Excel files; one for each level of the value model. The files all had eleven worksheets, one for each stakeholder group and one overview worksheet which linked to the ten other worksheets. This was performed in Microsoft Excel, since this program could provide an overview of all the statements per level of the value network, while maintaining the ease of scrolling through the statements, or hide groups of stakeholders. This is graphically shown in Appendix B, step 6. All schemes are available on request. A more detailed example of the analysis of the 82 sleep clinics is provided in Appendix A.

4.5 Additional Reliability Issues

There is always a danger of researcher bias in analyzing qualitative research, particularly since no statistical tests are used (Bryman, 2008). In order to increase the replicability and transparency of the research, a clear process of data analysis of the interviews including the code determination and coding strategies is extensively discussed in the previous section and all coding schemes are available on request. An example of the coding strategy is presented in appendix B. Concerning the reliability of the data gathering, the involved interviewees are anonymously mentioned in the report. This was mentioned before the start of the interview, since it may reduce the degree of socially desirable answers. All interviews were conducted in Dutch, the first language of the specialists. This was done in order not to exclude information due to language barriers. Also, the interview questions were designed so that they did not contain theoretical definitions. The notion of 'value' was avoided and instead replaced by for example 'important aspects of'. The expert interviews contributed to properly defined concepts before the other stakeholders were interviewed. The interviews were recorded and subsequently transcribed verbatim with the exact phrasing of the respondents, in order to not exclude anything beforehand. Gestures were not noted, except for the situation in which they were relevant for the content (e.g. a respondent pointing to a part of his face in order to explain a device). None of the twenty-nine interviewees objected to the recording of the interview. All 220 pages of anonymized interview transcripts, including their corresponding audiotapes are available on request. Subsequently, the interview transcripts were sent to the respondents by e-mail, in order for them to check whether the content covers their opinion. One interview was sent back with refinements by the interviewee. The construct validity was justified by using a type of data triangulation (Yin, 2009). Interviews are accompanied by academic literature, observations within the health clinics, and data from the websites of the sleep clinics. The use of in-depth interviews also increases the internal validity of the findings. Despite the low number of respondents per stakeholders, a wide range of stakeholders is selected who together cover a large part of OSA diagnosis and treatment in the Netherlands.

5. RESULTS

The findings are presented in a structured way, following the final coding scheme. The interview data are referred to as (IV #). An overview of the corresponding interviews is provided in appendix C. Furthermore, the findings of the desktop study on 82 hospitals are used to provide data for the care path section.

The findings are presented in six sections, each representing a part of the value network. The first section discusses the overall OSA level by presenting the care path for OSA in the Netherlands and additional matters. The second section presents the findings concerning the treatment options level and performance attributes and emphases on performance attributes the decision making actors choose a treatment. The third and fourth section show the findings of the treatment levels for respectively CPAP and MAD, focusing on the processes around the treatment. The fifth and sixth sections present the device level findings for CPAP and MAD, discussing important aspects of the devices. The chapter structure of sections 5.1 till 5.6 is graphically represented in figure 5.1.

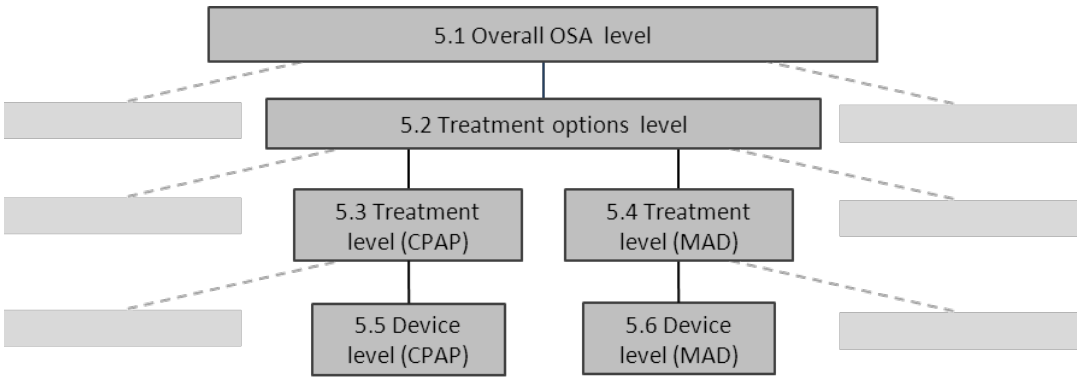

Figure 5.1 *– The structure of an OSA value network and arrangement of sections 5.1 – 5.6.*

5.1 OVERALL OSA LEVEL

First the care path for OSA diagnosis and treatment in the Netherlands is discussed. Next, the other findings concerning the overall OSA level are presented.

Care Path

The interviews show that OSA patients start in all cases with a general practitioner (GP) visit (IV 9, 12, 13, 21-24). The GP refers patients to another medical specialist, or can decide not to refer (IV 6, 7, 9, 13, 23, 24). In the latter case the patient remains untreated. Reasons for a GP not to refer to are: no recognition of OSA, the expected inconvenience of the (sleep)tests to the patient, the large costs of sleeping tests (although this is reimbursed) or no improvements are expected (IV 23, 24). GP referrals were found to be influenced by regional factors such as local agreements between hospitals and GPs (IV 2, 12, 14, 18, 23). After the first line treatment (GP), the second line of treatment for OSA are sleep clinics.

Sleep clinics from the interview data sample comprised a team of medical specialists within a general hospital; patients visit the ENT or pulmonologist in their polyclinic within the general hospital. Despite that all of the respondents worked within a general hospital, the Dutch Apneuvereniging (2012) reports also

independent second line sleep clinics within the Netherlands. Furthermore, third-line sleep clinics were found to treat complex cases and are often independent clinics and not a part of a general hospital (IV 21). The desk top study of Dutch hospitals shows that pulmonologists and ENTs are present within almost all sleep clinics (96%). Furthermore, sleep clinics have possession of neurologists (81%), OMS (40%), OSA nurse (35%), a dentist (25%) and psychologists (15%) (desk top study). This is shown in table 5.1. Most specialists works within the sleep clinic , but a part works part time at another institution. However, a larger part of the dentists (60%) work outside the hospital. The ratio of internal and partly external specialists is shown in table 5.2 in gray. Finally the desk top study shows that sleep centers occasionally collaborate with cardiologists, dietician and weight reduction therapists, who have not been found to be involved in OSA diagnosis and treatment, but play a role in the comorbidity of OSA and other diseases.

Table 5.1 *- Medical specialists within hospital treating OSA as reported on their website.*

Specialist present in hospital	Number reported	% reported
Ear, Nose and Throat specialist (Internal / External)	78 (73 / 5)	96 %
Pulmonologist (Internal / External)	78 (75 / 3)	96 %
Neurologist (Internal / External)	66 (61 / 5)	81 %
Oral and Maxillofacial Surgeon (Internal / External)	32 (27 / 5)	40 %
Special OSA nurse / practitioner (Internal / External)	28 (28 / 0)	35 %
Psychologist / Psychiatric (Internal / External)	15 (14 / 1)	19 %
Dentist or Orthodontist (Internal / External)	25 (11 / 14)	31 %

GPs cannot directly prescribe a sleep study (IV 23). Instead they refer to a sleep center that can decide to perform a sleep study. In 50% of the cases, the patient is seen one specialist at the sleep clinic. The other 50% sees two or more specialists (Apneuvereniging, 2012). In all interviewed clinics, anamnesis is performed, together with an assessment of the experienced sleepiness.

Table 5.2 – *Findings of a desk top study on the Dutch OSA care path; specialist intake after GP referral as reported on the websites of sleep clinics in the Netherlands.*

Specialist	Number	% of total
General intake (*often including multiple examinations and followed multidisciplinary case discussion*)	11	13,6%
ENT/Pulmonologist/Neurologist, depending on situation	29	35,4%
Always Pulmonologist	16	19,8%
Always ENT	9	11,1%
Always Neurologist	5	6,2%
Not mentioned	11	13,6%

The analysis of 82 hospitals/clinics in the Netherlands shows that the majority of the intakes (72,9%) is performed by an ENT, pulmonologists or neurologist. Eleven clinics (13,6%) reported a general intake and eleven cases (13,6%) did not report the intake procedure on their website. Of the 72,9% in which the intake is performed by an ENT, pulmonologists or neurologist, 29 (49%), sleep clinics report on their website that a GP should refer to an ENT in case snoring is the main complaint, a pulmonologist in case only OSA is suspected or a neurologist in case the GP expects also other sleep disorders to be involved. According to the websites of the sleep clinics, the desk top analysis shows that a GP should refer directly to the pulmonologist

(19,8%), ENT (11,1%) or neurologist (6,2%). Table 5.2 shows the percentages of intakes that followed from the desktop research. This percentages refer to the number of clinics, not the number of patients. Contrary to these findings, the Apneuvereniging (2012) shows that 33% of the sleep clinics has a general intake.

Next, patients undergo a sleep study. Six percent of the patients is excluded from a sleeping test after a sleep clinic visit (Apneuvereniging, 2012). Four different sleep tests are performed: Laboratory-based PGS (30%), ambulant PG (30%), clinical PG (20%) and ambulant PSG (20%) (Apneuvereniging, 2012). These sleep tests have been explained in chapter 2. PG is usually executed within the pulmonary center, whereas PSG is performed at the clinical neurophysiology department (IV 14, 16). Second-line institutions generally perform a single sleep study for diagnosis, whereas third-line institutions tend to use a double PSG (IV 16, 21) because this is a more precise. After - or in some cases before - the sleep study, the ENT performs a sleep endoscopy, and a chin lift in order to predict the clinical effectiveness of a MAD (IV 1, 3, 10, 11).

In case a CPAP therapy is chosen, Pulmonologists coordinate patients (IV 8, 10, 19). The titration, the process of adjusting the pressure and tailoring the treatment, is performed in a hospital by a pulmonologist, a pulmonology practitioner or an external company (IV 8, 14, 19). However, companies can perform the titration at the patient's home, or they organize titration sessions within the hospital. If MAD treatment is chosen, a dentist most often (61%) performs the treatment (viz. orthodontists, gnathologists and regular dentists, IV 2, 9, 11, 12, 15). This can also be performed by an OMS (in 26% of the sleep clinics). Additionally, the analysis shows that in some cases the MAD therapy is performed by an ENT (9%) or external company (6%). Once a dental imprint is made by one of these specialists, a dental lab produces the final device. MAD suppliers are companies making the device after an imprint is made by a medical specialist or dentist. In some cases a dentist or OMS takes over the whole therapy including consultations (IV 13, 15, 19), whereas in other cases the patients are still seen by their initial coordinating specialist, e.g. a pulmonologist (IV 9, 15). Patient follow-ups range from an annual inspection (IV 13), or a couple of visits (IV 6) to a single visit (IV 20). Often, a sleep study after three to six months (IV 13, 15) is performed in order to assess the effectiveness of the treatment.

Awareness and Underdiagnosis

It is commonly known among the medical specialists that OSA is seriously under diagnosed (IV 1-7, 9, 12, 13, 22-24). 66% of the patients was *not* yet diagnosed within four years (Apneuvereniging, 2011). In line with that, GP 1 states*: "I diagnose approximately two or three OSA patients per year; let's say one per thousand patients." […] "Yes, we often don't recognize it".* Even when OSA is suspected, GPs do not always refer. This is exemplified by dentist 3: *"I had a patient and told him to see his GP and ask for a sleep study, because I suspected OSA. But his GP told him: 'No, that's nonsense; it's not treatable in your case'."* However, several specialists ascertain an increase of the awareness for OSA (IV 9, 11, 12).

Due to the complexity of the disease pathophysiology which touches to different clinical disciplines, the importance of a multidisciplinary approach in the diagnosis and treatment of OSA was often emphasized within the interviews (IV 6, 10, 11, 13, 18, 20, 22). Moreover, specialists search for a solution within their own discipline (IV 1, 2, 6, 13, 22), The specialists are not used to think multidisciplinary, which can hinder the collaboration (IV 1, 2, 13, 18). An example is provided by dentist 3, who explains that dentists look at the

condition of the teeth, but do not or cannot make the decision of the importance of good teeth against that of good sleep. They are inclined to put good teeth on number one, since that is their job (IV 13). A second aspect that stands in the way of good multidisciplinary OSA care, is a financial incentive of decision making actors (IV 2, 13, 18, 22). Care givers get a financial compensation for their treatment, which can be an incentive not to refer to another specialist. Within the multidisciplinary team interview it was stated that: "*At the basis of such a successful multidisciplinary collaboration, is that you're not constantly fighting for your own solutions [...] and not being afraid of hidden agendas containing financial aspects. This is however a problem within other clinics."* It was furthermore found that specialist even asks for financial compensation when referring to another specialist. Dentist 3: "*Colleague dentists told me that they were approached by a pulmonologist who suggested them to pay €10,- for each patient he referred to their dentist's practice*".

5.2 TREATMENT OPTIONS LEVEL

The criteria on which specialists choose for a treatment are discussed, in order to identify how the decision process takes place between one treatment option or another.

A first factor where specialists base their decision on is the *'clinical effectiveness';* the measureable effectiveness of a therapy in a laboratory setting, which is often expressed in an AHI reduction. Three out of four pulmonologists state this to be the most important factor in choosing a therapy (IV 7, 8, 9); pulmonologist 2: "*Reducing or eliminating apneas is the most important in a therapy*." ENTs and OSA nurses state the AHI to be very important as well, next to the general health status of the patients, including the overall complaints.

Second, a patient's '*compliance*' to his therapy plays a major role in achieving an overall effective therapy. Dentist 3: "*It is a treatment that works only when you're using it. Soon as you stop using it, the apneas come back immediately*." CPAP and MAD were compared with wearing glasses: once you put off your glasses, you immediately stop seeing clear. A difference can be seen in short and long term compliance (IV 1, 3). Short term compliance refers to the number of hours per week the device is used, long term compliance refers to how long the patient is compliant to the therapy in months (IV 3). Both long and short term compliance were found to be heavily influenced by the comfort of the therapy and the experienced reduction in complaints caused by the OSA (IV 8, 10, 11, 21, 22). Current compliance research was argued not being representative for the Dutch situation (IV 11, 16). The compliance research is often conduced in countries (mainly US) where often only CPAP is covered by the health insurance companies. In a country where every patient gets a CPAP, the compliance will be lower than in a country where only severe patient that benefit most from it get CPAP (IV 11, 16). The same goes for MAD. In case a patient is carefully selected for a therapy, the compliance will be higher than random a non-specific selection cohort of patients. In the Netherlands. the patients are carefully selected, but it was stated that patients in compliance research are often not (IV 11).

Third, the *'experienced effectiveness'* of the therapy is the improvement that a patient experiences in the reduction of OSA complaints. In this respect, the experienced effectiveness is positive when the total improvement of complaints caused by OSA is larger than the experienced discomfort of the treatment (IV 8, 9, 10, 11, 14, 15, 21). Especially among the mild and moderate OSA patients there can be a discrepancy between the realized AHI reduction and the experienced improvements in complaints such as day time

sleepiness (IV 10, 16, 22). The experienced effectiveness was found to play an important role for the patient's motivation to continue the treatment (IV 8, 9, 10, 11, 14, 15, 21).

Fourth, the '*comfort'* of the treatment is important (IV 6, 8, 10, 20). Within the boundaries of an effective therapy, specialists try to "*make the therapy as comfortable as possible*" (IV 22). In the case of severe OSA patients, comfort becomes less important and the clinical effectiveness comes first (IV 7, 11, 15). According to ENT 4: "*Comfort certainly plays a role, but in the first place we have a problem that needs to be solved*." Hence, a high comfort is more important within the mild or moderate patients in order to achieve an indispensable level of compliance (IV 6). Besides, patients ambiguously experience comfort (IV 5, 16, 17, 19, 20). For instance a young patient who travels a lot has relatively more benefits from MAD compared to CPAP than an old patient who never travels.

Also another performance attributes were identified, but found less to be important compared to the aforementioned effectiveness, compliance and comfort. A first, the price of a treatment can play a role. CPAP and MAD were found comparable in the total price (IV 8, 10, 11, 14), making it not a decisive factor. And as explained by pulmonologist 3: "*Price is more of concern to the reimbursement companies, not to us*." However, when a therapy is too expensive for the clinical effectiveness, it is likely not to be reimbursed (IV 5, 16). Second, MAD is a tailored device and it cannot be used for another patient once it is made (IV 6, 7). CPAP devices can easily be reused on other patients in case a patient turns out not to be compliant for CPAP, which can play a role in choosing CPAP. A third factor, adduced by pulmonologists, is that the patient can immediately start a CPAP treatment (IV 6-8). A fourth factor are the clinical guidelines. They are in most cases used in the decision for a certain treatment (IV 7, 10, 13, 22). The specialists use the guidelines in most cases, but are not afraid to derogate from it (7, 13, 22). Fifth, specialists state that a treatment method should be proven effective and safe in the academic literature before they start using it (IV 1, 3, 4, 9, 21). ENT 1: "*You should always decide evidence based*. Sixth, as explained in chapter two, the anatomy of a patient may exclude patients from MAD.

Another point is that specialists argue for the combination of treatment methods (IV 1, 9, 17, 19). This can be a combination of MAD and CPAP, in order to reduce the pressure and thus increase comfort. Or a combination of MAD and a position trainer in order to increase the effectiveness (ibid).

5.3 Treatment Level: CPAP

The treatment level encompasses the system around one single OSA treatment. This includes the titration, coaching and guidance and follow-ups. First, the findings that concern both treatments are presented. Thereafter some specific statements for CPAP are made.

Among the interviews it was widely supported that good guidance and coaching is of great importance for the OSA treatment (IV 6, 8, 10, 13, 14, 18, 19). Pulmonologist 1: "*The devices always get all the attention, but I think that the care around the devices is very important as well […] and underrated*". However, this is not always financially feasible (IV 8, 14). In the words of the interviewed neurologist: "*I would like to offer an intensive guidance of the therapy […] but we can financially not afford the effort of providing that guidance"*.

In particular the first weeks of the treatment were found to be important in order to achieve a long term compliance of the therapy (IV 6, 8, 19). As a significant part of the OSA patients is obese, a recurring point of discussion is the importance of a holistic therapy including a weight reduction program (IV 1, 8, 9, 11, 14, 21, 22, 24). OSA patients show disrupted hormonal cycles, causing metabolic disorders that hinder weight reduction (IV 1, 16). ENT 5: *"You should provide patients with a full therapy; treating the OSA and combine this with weight reduction programs. Only then you can actually treat a patient […] These [obese] patients require good coaching, otherwise they'll destroy their knees or get heart problems. […]. Unfortunately we don't get any insurance money for this, so we cannot offer this type of holistic therapy."* Agreements with the insurance companies play a role in choosing a supplier (IV 7, 10). In other cases the supplier was historically determined (IV 7, 11). Specific for CPAP treatment, the pulmonary department is often in charge. They manage the titration and follow-ups, although titration can also be performed by an external company. Aside from the previously mentioned matters, the follow-up processes were found to be sufficient for CPAP treatment within the data sample. Besides, the suppliers' service plays a role for the physicians in choosing a brand. Pulmonologist 2: *"[CPAP] suppliers compete on the service they deliver, for example in providing the compliance data, rather than on the device they deliver"*.

5.4 Treatment Level: MAD

The general statement concerning guidance and coaching as discussed in the previous section, also play a major role for MAD treatment. MAD titration can be performed by several types of physicians including an OMS, dentist of ENT and requires a series of follow-ups before the right protrusion is set (IV 13). MAD treatment is increasingly performed outside the hospital, by regular dentists who are not enough specialized in OSA treatment to make educated decisions (IV 2, 13, 15, 22). A part of the regular dentists takes over the whole OSA treatment process, for example in the Nijmegen area (IV 15, 19). According to the interviewed OMS this is a dangerous trend, since dentists are not sufficiently trained to treat OSA patients (IV 15). Moreover, it becomes unclear who is in charge of the follow-up process and the monitoring of the disease. This is not a task for a regular dentist, who is not trained for this. But after a patient is sent to a regular dentist to perform a MAD treatment, the initial leading expert may withdraw its responsibility of the process. The service of supplying companies was found to be important for MADs as well. The five year warranty for MADs plays a role in choosing what supplier to choose from (IV 13, 15, 17).

5.5 Device Level: CPAP

Within this section the findings of the 'system' CPAP device CPAP level are presented. An important factor concerning the overall comfort was found to be the mask (IV 5-8, 10, 16, 18-22). The mask quality has improved over the last years (IV 6, 7, 10), which directly impacts the overall comfort of CPAP devices (IV 6, 7). Within the multidisciplinary team interview it was pointed out that: "*it's not about the machine, but about the masks*". Complaints concerning the masks when using CPAP devices include displacement of the mask during the night (IV 19) and not accurately fitting on the patient's face (IV 7, 18, 19, 21), both resulting in leakage (IV 7, 18, 19). Furthermore, the sound of the device plays a role in the comfort (IV 6, 7, 18, 21), and is reduced within the last years (ibid). Also, the design of the machines was stated to be improved (IV 6, 8, 21).

Although the device looks more 'fancy', OSA nurse 4 argues that most users are old people who prefer a simpler design. But medical specialists and insurance companies actually buy the devices and they are more intended to buy fancy looking devices (IV 21). Furthermore, heated hoses and moistening can play a role, but was not found to be of main importance (IV 5, 16, 18, 19). The '*effectiveness'* of the device is of major importance (IV 6-8). However, devices are currently not competing on effectiveness, since this is already warranted by all the availably machines (IV 6, 7). The interviewed specialists see little development in the CPAP devices over the last years (IV 14, 20). The specialists notice the quality of the current devices levels off and they do not need or expect any other major developments (IV 6, 7, 8, 10, 14, 18, 20, 21). Another factor concerning comfort is the size of the device (IV 7, 10, 20, 21), which has also improved to a level on which no major developments are expected (IV 7, 10, 21). Two of the pulmonologists did not recognize any major differences among the available CPAP devices (IV 6, 7). For example Pulmonologist 2 explains that in the case of CPAP: *"The supplier was historically determined, but the differences [between devices] are so small, that does not play a major role. I don't have a strong preference for a certain brand"*. Different CPAP producers have been found to be active in the Netherlands, including Respironics, ResMed. The machines are supplied by the companies ComCare Medical, Farmadomo, Tefa, Total Care and Vivisol

5.6 Device Level: MAD

'Comfort' was pointed out as an important factor for MAD devices (IV 1, 2, 10, 12, 13, 15, 17, 19). Comfort includes that the "*the device has to fit well and feel comfortable in your mouth, not too big or inconvenient"* (Dentist 3). An important factor in the comfort is the possibility to open the mouth while wearing a MAD (IV 5, 13, 15, 17) [*2]. This makes duo-blocks more preferred compared to mono-blocks. Another reason for using duo-blocks is the possibility to adjust the protrusion without sending the device back to the lab. Although, when the protrusion is well set at the first time, the effectiveness between mono- and duo-blocks does not differ (IV 2). But a patients' mouths can change over time (IV 13). Another factor influencing the comfort is a soft inside layer in the device (IV 13, 15, 17). This soft inside layer increases the comfort of the device.

The *clinical effectiveness* of MAD devices is of great importance, but is not yet found to differ among the different available devices. It was found to depend on the protrusion (IV 2, 10, 17). However, there has not been a sufficient research that compares the different available devices on their effectiveness (IV 3, 11). Regarding effectiveness studies for MADs, dentist 1 argues: "*Different types of MADs have been compared in literature. However, these papers never show the used protrusion and vertical displacements.*" In case different protrusions and vertical displacements were used, the differences in clinical effectiveness of different devices cannot be verified.

Another factor that was found to influence the quality of the device is the *durability* (IV 11, 13, 17). Concerning the durability, two factors were identified; the type of material and the construction of the device (IV 11, 13, 17). The construction should be strong on the points where the most force is distributed. Furthermore, the

[2] Interview 17 represents a MAD producer selling adjustable, soft-inside duo-block MADs. One should therefore be cautious with statements of number 17 within section 5.5 of the results.

load distribution over the teeth should be good (IV 10, 13, 17). Also the *hygiene* plays a role, the devices become unhygienic after a certain time and need to be cleaned frequently (IV 2, 13, 15, 17). Devices with soft inside layers were stated to be less hygienic compared to other types (IV 2). However, the additional comfort of a soft inside layer plays a more important role than the hygiene reduction (IV 13, 15, 17). *The warranty* is also important for the device (11, 13, 17). The devices are covered once per 5 years by health insurance. A 5 years warranty period guarantees the patients for not buying a new one out of pocket.

Patients can adjust the protrusion themselves when using adjustable devices. Although this adjustment options is often seen as an advantage (IV 1, 12, 13, 20), dentist 1 warns for adjustments by patients. In his eyes, only specialists should adjust the protrusion, since this can make or break a treatment. Patients can set too high a protrusion, even up to 120%, or adjust it to the wrong direction (IV 2). Furthermore, concerning the adjustability of the device, dentist 1 concluded with "*adjustable devices are more easy to use for doctors and patients, but mono-blocks can be effective as well.*" Finally, specialists prefer a device that includes a read-out function on the MAD devices (IV 14, 21).

Furthermore, specialists see little developments in the MADs (IV 6, 9, 19, 20). MAD was stated to be theoretically limited to a certain degree of effectiveness (IV 1, 2, 17). The MAD producer acknowledges that "*We cannot improve the effectiveness significantly on the principle of advancing the mandibular, instead we should look for new combinations of therapies with for example a position trainer.*" After MAD was covered by the health insurance as a treatment option for OSA in 2010, an increase in MAD sellings was seen. Other OAs, such as tongue retainers and boil and bite devices were, in line with the academic literature, found not to be effective (IV 1, 2, 6, 8, 13, 17). Five different producers of MADs could be identified in the interview data (IV 1, 2, 3, 5, 10, 11, 13, 15, 17). The five types of MADs are shown in figure 5.2. SomnoMed is currently market leader with approximately 60 to 70 per cent market share in the Netherlands (IV 3, 5, 17).

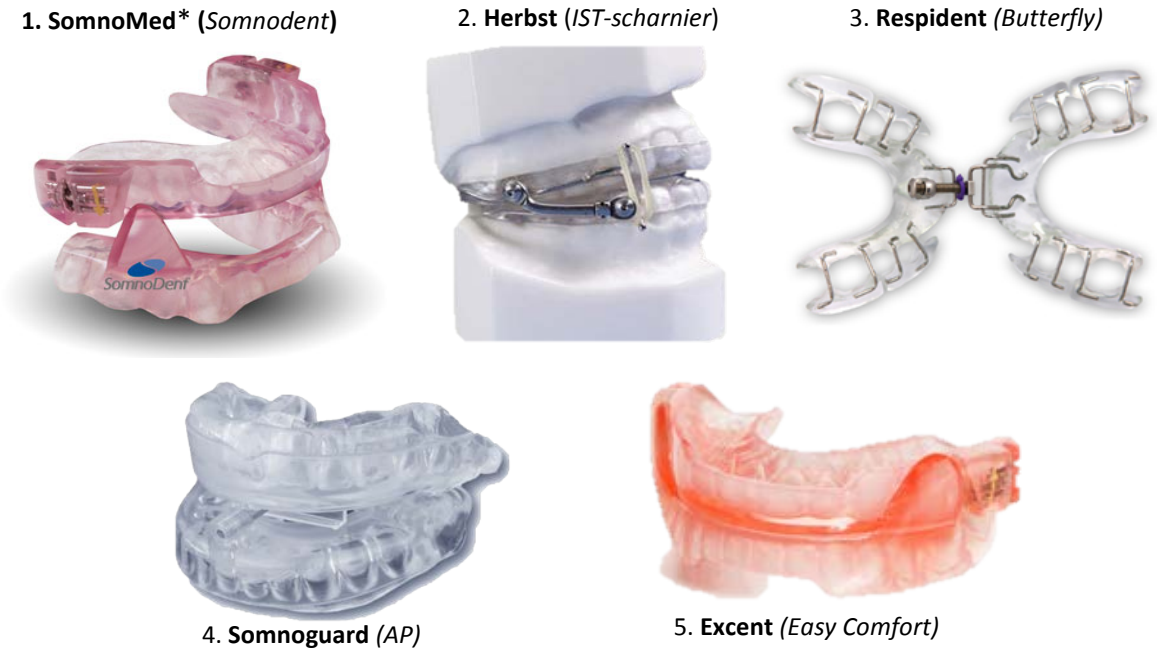

***Figure 5.2**- Five different MADs available on the Dutch market. **Company name** (product name).*
**Market leader (Somnomed, 2013 and more. For full reference, see figure references at the end of the report).*

6. ANALYSIS

Based on the findings as presented in chapter five, this chapter presents an analysis of the CPAP and MAD value network configuration and the potential of MAD therapy to serve OSA patients and take over the CPAP market. First, an answer to the first research question is provided in 6.1, which discusses the OSA care path. Thereafter, section 6.2 presents the key performance attributes, i.e. the most valued performance attributes on which treatment options compete. This includes an assessment of the relative importance of key performance attributes for the three lower-ordered levels of the CPAP and MAD value network and provides an answer on the second research question. Thereafter, in 6.3 the third research question is answered by providing an analysis on the potential of MAD to serve OSA patients and take over the CPAP market.

6.1 THE CONTEXT OF OSA TREATMENT: THE OSA CARE PATH

This section answers the first research question; "*What does the Dutch context for OSA treatment look like; which decision making actors are in what way involved in the care path OSA patients can go through?".*

The 'overall OSA level', as delineated by the OSA care path sketches the context in which the competition between CPAP and MAD takes place. It seems that patients can go through a lot of different care paths and it was found that OSA diagnosis and treatment in the Netherlands varies among sleep clinics and regions. This is graphically summarized in figure 6.1.

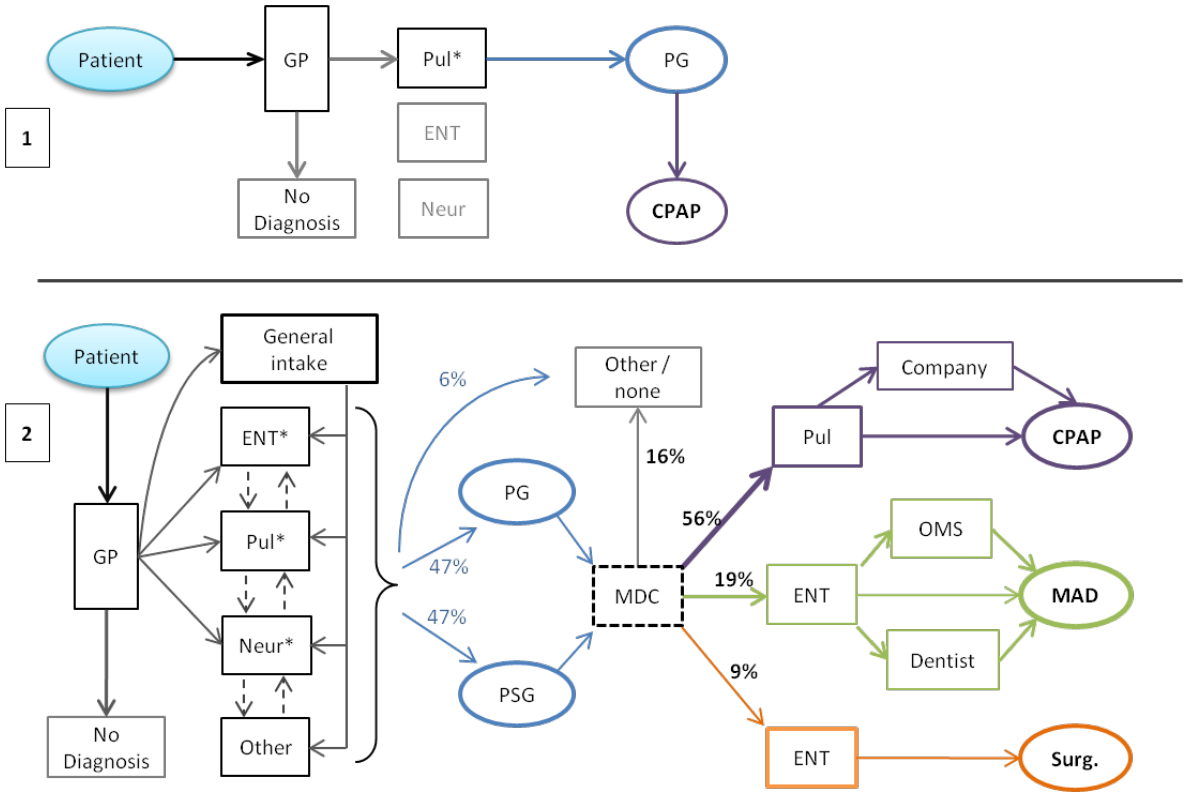

Figure 6.1 *– Care Path for OSA diagnosis and treatment in the Netherlands*
[1] The most simple care path that was identified. [2] A more comprehensive care path for the Dutch situation. *Anamnesis and a day time sleepiness test (ESS) is performed | GP = General Practitioner | ENT = Ear, Nose and Throat specialist | Pul.=pulmonologist; | Neur=neurologist | 'other' refers to other medical specialist or treatments | PG=Polygraphy | PSG=Polysomnography | MDC=Multi-Disciplinary Consultation | OMS=Oral and Maxillofacial surgeon | Surg.=ENT surgical intervention | blue lines refer to the sleep study, purple=CPAP treatment, green=MAD and orange=surgery.

The first path [1] shows the most basic identified route. In this case, the GP suspects OSA and sends the patient to a pulmonologists, who executes a PG and starts a CPAP treatment. The second care path [2] shows the multiple routes OSA patients can follow from a diagnosis to a treatment. It shows that a GP sends a patient to an ENT, pulmonologist, neurologist or a general intake. The general intake can be performed by an OSA nurse or again an ENT, pulmonologist, neurologist, who in their turn send the patient to one of the other specialists. Thereafter will be decided to perform a PG or PSG. The results of these studies are then discussed within a multi-disciplinary consultation (MDC) and a therapy is proposed, which will be determined in discussion with the patient. Notably, the MCD may be absent in some sleep clinics or only used in complex cases. An ENT performs a sleep endoscopy at the majority of the patients. This can either be performed before the sleep study, or thereafter. The percentages in figure 6.1 are based on two reports by the (Apneuvereniging, 2011, 2012). The 2012 report by the Apneuvereniging discusses the different percentages of referrals, but does not give such an extensive care path as presented in figure 6.1.

6.2 KEY PERFORMANCE ATTRIBUTES

This sections presents the key performance attributes of CPAP and MAD treatment on each level of their value network. This forms the basis for answering the second research question: *"How do the decision making actors within the OSA care pathway value the performance attributes of MAD and CPAP?"*.

Treatment Options Level

This system level clearly shows the multi-actor decision structure that characterizes health care. Patients, insurers and different medical disciplines are involved in the decision for a treatment. The insurers create a set of boundaries on which treatment decisions are based. However, physicians can deviate from this in specific cases. Patients play a role in influencing the decision of physicians. However, the medical specialists were found to be most explaining in the choice for one treatment, since the insurers and patients rather set the boundaries within a decision by medical specialists is made. The medical specialists are therefore the main unit of analysis in the identification of key performance attributes.

Key performance attributes in the treatment option level are important for the choice by medical specialists of an OSA treatment. In almost every interview the importance of the key performance attributes mentioned at the treatment options level. The performance attributes 'compliance' and 'clinical effectiveness' were found to play a key role. Also the 'comfort' of a therapy is of main importance, particularly for the purpose of positively influencing the compliance of a treatment. However, the compliance is only of importance in case the clinical effectiveness is high enough and *vice versa*. In other cases, the treatment is not effective at all. For this reason the researcher introduced a new key performance attribute on which treatments are chosen that combines the compliance and the clinical effectiveness: the *'True Effectiveness'* of a treatment. This term is more commonly used in OSA literature (e.g. Randerath, 2002) and encompasses the overall effectiveness of the therapy in reducing complaints and measureable negative effects of OSA. The true effectiveness is determined by the objective clinical AHI reduction in combination with the short- and long-term compliance to the therapy. Statements about the true effectiveness were also found within the interview data. The true effectiveness can be measured by using the 'mean disease alleviation' (MDA) index (IV3). This is the total

average number of prevented apneas. An overview of the relations between the identified key performance attributes is shown in figure 6.2. It can be seen that the true effectiveness is determined by the clinical effectiveness (measured in AHI reduction) and the compliance (measured in average hours per night and the long term compliance measured in months). The compliance in its turn is determined by the trade-off between the experienced effectiveness of using the therapy against the discomfort of the device. The relation between clinical effectiveness and the experienced effectiveness is gray and dashed, because this relation was found to depend on the OSA severity. Overall, these proposed relations can explain why severe patients often get the more effective and less comfortable CPAP, whereas mild and moderate patients are more eligible for MAD therapy.

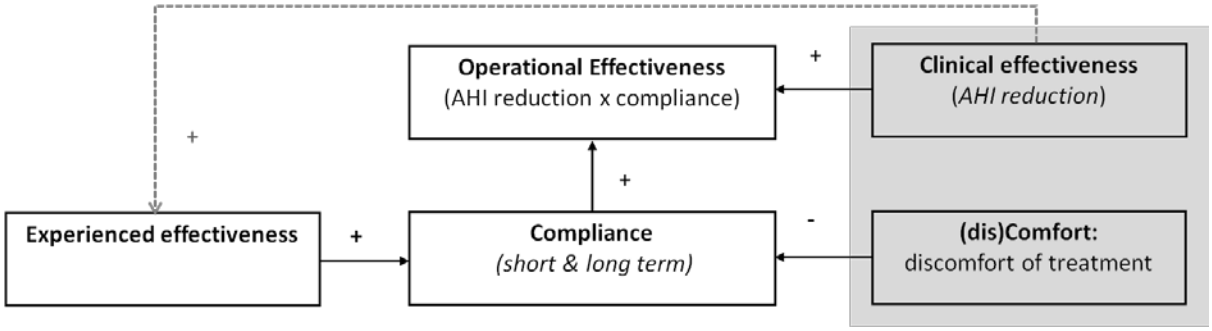

Figure 6.2 *– Key performance attributes and their relations at the treatment options level*

The clinical effectiveness and the comfort of the therapy are directly influenced by characteristics of CPAP and MAD treatment. The gray rectangle in figure 6.2 shows the factors that are influenced by technology factors. The experienced effectiveness is patient depended. The other two key performance attributes, compliance and true effectiveness a result of the other three. To this end, it is argued that the *clinical effectiveness* and the *comfort* of a treatment are the two most important performance attributes of OSA treatments as valued by medical specialists to choose for one treatment or another.

Treatment Level (CPAP)

Performance attributes at the treatment level of the CPAP value network play a different role. Patients are not sold, but referred to a certain specialists that manages the treatment process. Performance attributes act more as important aspect of the treatment. Suppliers in this level have no typical supplier-customer relation but tend to choose themselves or their own colleagues to treat a patient. A treatment consists of process components (guidance and coaching, follow-ups and titration) and the devices itself. Pulmonary departments can be seen as the main suppliers for CPAP treatment. *Guidance and coaching* were found to be a key performance attribute within both of the treatment options levels of CPAP and MAD. Within this level there was an identified importance of an *holistic therapy*, including weight reduction programs, which are currently not covered by the health insurance. Furthermore, it was found that the provided *service* by the CPAP providing company can be equally determinative in choosing a brand as the device itself.

Treatment Level (MAD)

The components of MAD treatment are rather similar to the CPAP treatment components. The provider of the treatment, however, is less obvious. It can be an OMS, dentist, or a combination of a dentist and ENT.

Specialists seem to struggle with the responsibility of the follow-ups in the case of MAD treatment, since MAD treatment involves multiple specialists of whom the one that makes the devices is not the one doing the diagnosis process. Different than from the CPAP treatment, a good *organised process* is yet underdeveloped, but important. The service of MAD providing companies and guidance and coaching plays an important role in choosing a supplier. The service includes warranty, fast delivery and trainings to dentists.

Device Level (CPAP)

The system 'CPAP device' is built out of the components mask, hose and pressure machine, but also comprises properties like size, sound and pressure controlling system. Being higher-level suppliers, pulmonologists are the most important decision making actors (customers) that value the performance attributes of the CPAP devices. Of the identified performance attributes, the *mask quality* was found to be the most important differentiator in explaining the overall comfort of the device. At the treatment options level, overall comfort plays a role in the decision for one treatment or another, whereas at the CPAP device level, it plays a role in the decision for a certain CPAP device or another. Figure 6.3 presents the identified key performance attributes and their relations. It can be seen that the comfort is influenced by the air pressure control system, hoses, mask quality, size and sound. As can be noted in figure 6.3, the key performance attributes in the device level relate to the higher order level key performance attributes in the treatment options level (being comfort and clinical effectiveness). The clinical effectiveness of the devices is already on a maximum demanded level; further improvements will exceed the demanded level of clinical effectiveness.

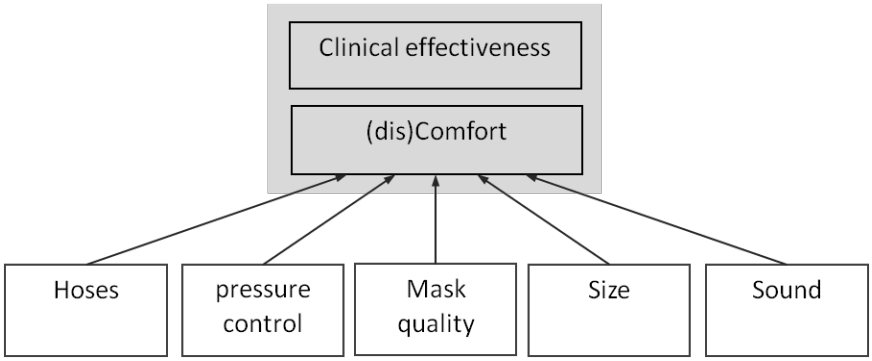

Figure 6.3 *- Identified key performance attributes in CPAP devices and their relations to the higher-order treatment option level.*

Device level (MAD)

The device level MAD contains the components of a frame including its materials and construction, soft inside layer and adjustment gear. Dentists, OMSs and ENTs involved in MAD treatment or MAD screening are the most important decision making actors that value the performance attributes of MAD devices. The *clinical effectiveness* and the *comfort* - both a key performance attribute in the higher order treatment options level - also play a role in the lower-order MAD device level. Although they manifest differently in a MAD.

Comfort is expressed by a number of factors, of which the most explaining is how well the device fits in the patient's mouth. How well the device fits was found to be influenced by the thickness of the device, an absence of sharp parts and, possibility to move the jaw, the use of a twin-block, a soft inside layer and the right design and shape of the device. In its turn, the force distribution over all the teeth is fully determined by

the design of the MAD. Furthermore, the durability was found to be an important factor, which is determined by the design and the use of strong materials. A soft inside layer increases the comfort, but has a negative influence on the hygiene and durability of the device. A longer-term discomfort in terms of teeth damage can be reduced by the right force distribution and protrusion distance.

The *clinical effectiveness* among MAD devices is not found to be significantly different, and was thus not identified as a differentiator. However, an accurate protrusion influences the balance between discomfort and clinical effectiveness; if the protrusion distance is too high, the discomfort is too high for the experienced effectiveness or, the clinical effectiveness is too low in case the protrusion distance is too small. Adjustable devices allow for more precise protrusions and corrections over time, thus influencing the clinical effectiveness. The clinical effectiveness is also influenced by the design of the frame. A bulky MAD causes rotation of the lower jaw, which counteracts the protrusion. The frame design seems to play a less important role, since all devices are that respect comparably constructed.

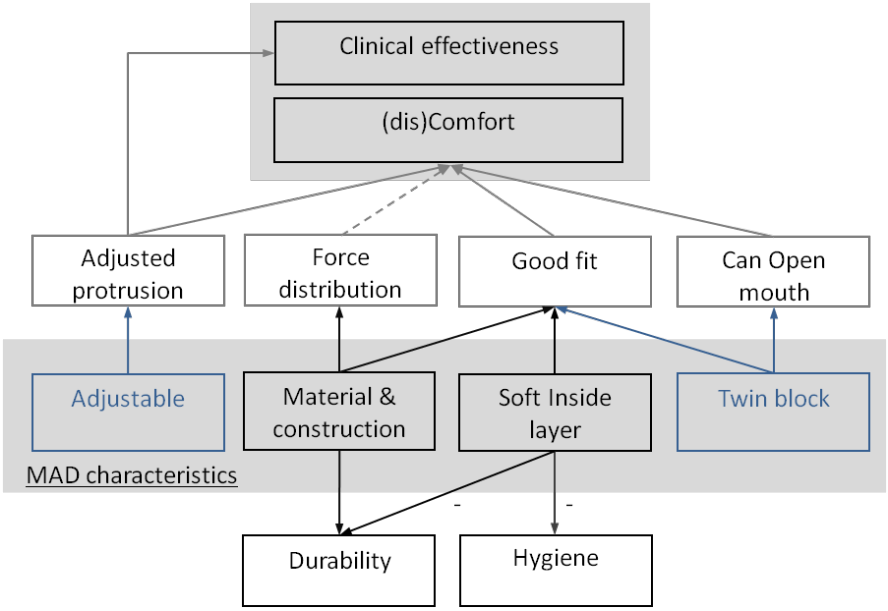

Figure 6.4 *- Identified values in MAD devices and their relations. Blue boxes are already warranted by the all of the available options. Dashed line to comfort indicates a longer term discomfort, as opposed to direct discomfort.*

Figure 6.4 shows important factors and their relations. It can be seen in the top left that discomfort and clinical effectiveness are two key performance attributes in a higher-order level that play a role in the device level as well, but manifest in other product characteristics of MAD. How comfort is gained in the device level can be seen when zooming into the second row in figure 6.2. Comfort is influenced by the 'protrusion', force distribution', 'good fit' and the possibility to open the mouth. Of these factors, 'good fit' was found to be most explaining for an increase in comfort. These factors are however no product characteristics and need to be explained by the underlying technological factors that are a device characteristic. In order to do so it was deduced that the materials and construction, soft inside layer and duo-blocks influence the performance attribute 'good fit', which was verified in the interview data. Furthermore, it can be seen in the lowest row that the 'durability' and 'good fit' have a thicker boarder. This is because those factors were found to be important the durability was found to be important. Two blocks 'adjustable' and 'twin block' in the lower middle row are blue, since all currently availably devices already contain these options.

6.3 MAD'S DISRUPTIVE POTENTIAL

The following section provides an answer on the third research question: *"What is the potential for MAD treatment to take over the current CPAP market?"*

MAD expresses itself better in key performance attribute 'comfort' and less in 'clinical effectiveness' compared to CPAP. Both technologies are not expected to increase their performance in '*clinical effectiveness'*. The previous sections show that decision making actors within the treatment option level do not demand more clinical effectiveness than CPAP currently provides. Considering Christensen's (1997) mechanism of disruption, this can create room for a disruption. In case CPAP keeps developing, its performance can exceed the demand, which leaves room for a less performing technology (MAD) to provide a cheaper solution. However, this is not likely to be the case. Most importantly, MAD is limited to a theoretical maximum clinical effectiveness, making it highly unlikely to serve the severe OSA patient group. Furthermore, also CPAP is bounded to a certain maximum in effectiveness, since it cannot increase beyond preventing more than zero apneas, which takes away the possibility of a high over-performance.

A technology can then be disrupted by another technology that can provide the demanded performance for a lower price. In the case of CPAP and MAD, it would be useful to look at the 'discomfort', instead of its costs. The costs in Euros is rather similar, but the comfort becomes less in case of a more clinical effective treatment, or device settings. The performance is in that case defined by its clinical effectiveness. The most demanding customers in that case are the severe OSA patients that need a high clinical effective treatment and are willing to pay the 'price' of a higher discomfort. Figure 6.5 provides a simplified graphical overview of the performance development (in clinical effectiveness) of the two studied OSA treatment technologies. The lines are estimated, based on the interview outcomes and their analysis. It shows that the lines deflect, instead of developing in the same pace as show in Christensen and Rosenbloom's (1995) example, which is presented in dashed lines and a red cross. The deflect of the line is caused by MAD's theoretical limit to improve clinical effectiveness and CPAP's limit of preventing more than zero apneas. MAD is not identified as a disruptive innovation that has the potential to take over the whole CPAP market including the severe patient groups.

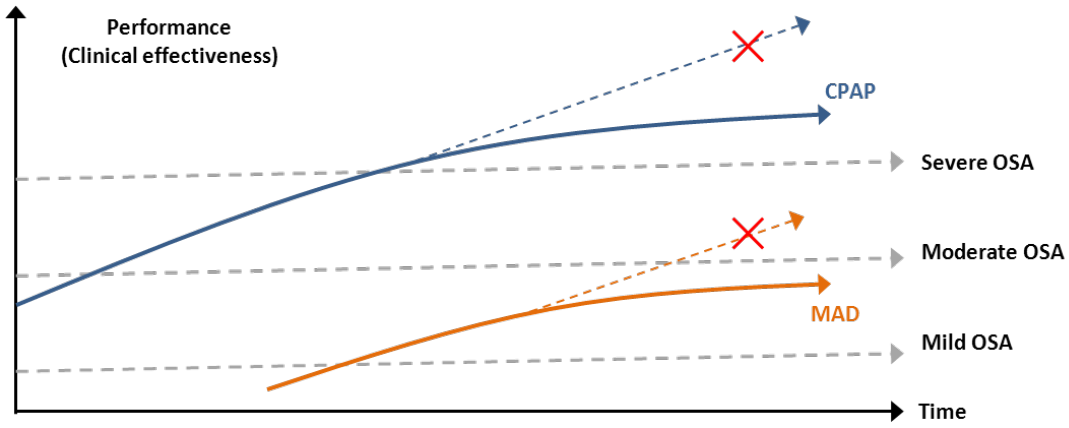

Figure 6.5 *– Simplified representation of CPAP (blue) and MAD (orange) performance development over time*

7. STRATEGIC IMPLICATIONS

Several strategic implications can be derived from the identified performance attributes and MADs disruptive potential as discussed in chapter six.

CPAP is more likely to serve the severe OSA market and MAD the mild OSA market. The strategic battlefield between CPAP and MAD is located between the severe and the mild patients group; in the moderate patient group. This is where CPAP and MAD technology should focus on concerning their competition. CPAP could serve more moderate patients when it increases comfort, since its clinical effectiveness is already above the demanded level for the moderate patients group. On the contrary, MAD should focus on an improvement in clinical effectiveness. Since both technologies are bounded to a certain maximum degree of comfort (CPAP) and clinical effectiveness (MAD), it may be fruitful to look at a combination of treatments. In order for MAD to increase effectiveness and gain ground in the strategic battlefield of the moderate OSA patients, it can search for combinations with position trainers. CPAP can increase comfort in case its pressure can be reduced. This can also be achieved with a combination with position trainers.

The emerge of MAD as an alternative OSA treatment has also broader consequences for current CPAP providing companies. The analysis shows that the field for OSA treatment is in development. Moreover there is a trend towards a better patient selection. CPAP providing companies are used to provide their 'one size fits all' devices to the majority of the patients. But if these CPAP providing companies still want to serve the broad OSA treatment market, they will need to diversify their treatment portfolios in order not to lose patients to newcomers who do offer these alternative solutions. Alternative treatments require better patients selections, because they are preferred in a more specific part of the OSA patients.

The analysis of the Dutch OSA care path shows a clear need for a better diagnosis. A simple test that can be provided by the GP. This reduces the referral barrier for GPs. Once the patient has been referred, the analyses revealed a need for a less costly diagnosis process. Improving on OSA screening and OSA will result into more diagnosed patient that consequently needs a treatment. This will enlarge the entire OSA market, including patients that need CPAP.

Furthermore, the analysis provides insights for current and future MAD producers regarding the aspects on which competition between MADs takes place. SomnoMed is currently market leader with their Somnodent device. They produce a twin block, adjustable, soft-layered and durable device. The company Except took over their design, also using a soft inside layer (see picture 5.2). Except's 'Easy Comfort' is cheaper than Somnodent (IV 15). This can be an indication for a starting price competition on the Somnodent design. The Somnodent and Except design may become a dominant design[3]. This is expected for a number of reasons. This device meets all the preferences of the medical specialists, it has over two third of the Dutch market and other companies bring devices to the market that are similar in design and product characteristics for a lower price. Because the Somnodent device already possesses the features that are currently demanded by the market, it will be hard to compete on product design for a higher market segment. The features can then be

[3] For an explanation of a dominant design, see Utterback (1996)

too good for the market demand and consequently offer too high a price for their devices. Another option can be to break in a lower market segment. Such low-end devices have already been proven ineffective in the treatment of OSA and do not get reimbursed in The Netherlands.

8. CONCLUSION

The aim of this research was to identify the value network around OSA treatment, with specific focus on CPAP and MAD treatment, using Christensen & Rosenbloom's (1995) notion of value networks. In doing so, an assessment was made of the *context* in which the competition between CPAP and MAD takes place, *decision making actors* within this (business) system and *key performance attributes* on which the technologies are valued by the actors within this system. The context of a competition between two medical treatments was delineated by the 'care path'; routes an OSA patient can go through from a first diagnosis until a final treatment. Four system levels of the CPAP and MAD value network were assessed; the general OSA, treatment options, treatment and device level. The levels delineations were based on criteria that were derived from the way Christensen & Rosenbloom (1995) demarcate their system levels and subsequently tailored for health care. All together, the research provides an answer on the main research question:

> *"What is the configuration of CPAP's and MAD's value network for the treatment of OSA in the Netherlands and which strategic implications for CPAP producers can be derived from this?"*

A care path analysis was added to the value network, in order to analyze the two medical treatments. By establishing an overview of the OSA care paths in The Netherlands, it was found that after a GP referral, OSA is treated in general hospitals, starting in sleep clinics to determine the severity of the disease. This resulted in a system-level overview of involved actors. OSA diagnosis and treatment in the Netherlands was found to vary among sleep clinics. Specialists would like to have precise, but cheaper OSA diagnosis solutions. Ten actor groups have been identified, of which the ENT and Pulmonologist are most important in choosing a treatment. A need was identified for simpler and cheaper first OSA diagnosis. As a second step, the key performance attributes based on which actors choose a treatment or device were identified for each level of the value network. This is graphically presented in figure 8.1.

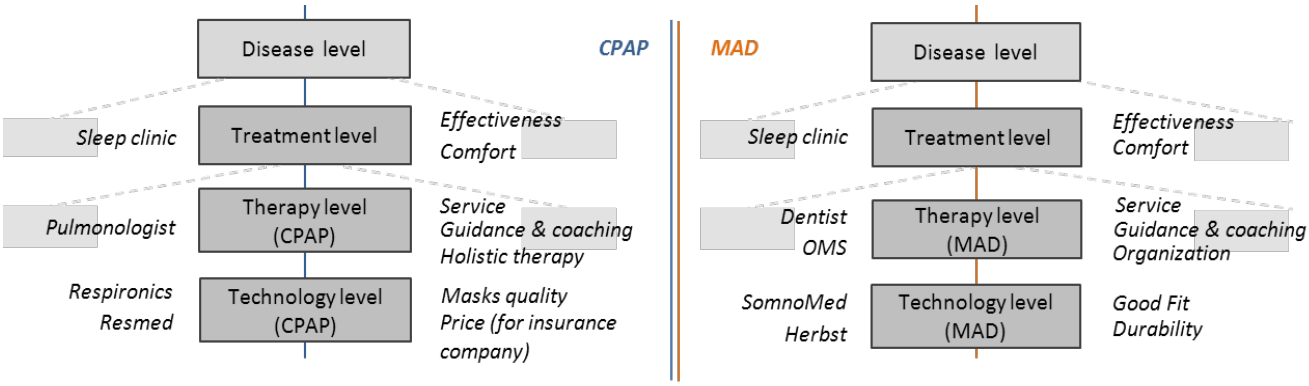

Figure 8.1 *The value network for MAD & CPAP for OSA treatment, including important decision making actors (left from the middle) and key performance attributes (right from the middle) for each level of the value network*

The first level provides the context of the innovations and thus has no performance attributes. Key performance attributes in the treatment options level show that a device for OSA treatment should be effective and comfortable. Together, these two factors contribute to a true effective treatment. Good guidance and coaching are key performance attributes among the interviewed medical specialists. The medical device company's services like warranty, providing information (in the case of CPAP), training, delivery time and overall service were identified to be important as well. When zooming in on the sub-system

CPAP device, the mask quality was found as the most important differentiator. MAD devices compete on a good fit and the durability of the device. In order to compete, MADs should be twin blocks, adjustable, soft-layered, well-constructed and durable.

MAD is in general found to be more comfortable, whereas CPAP is proved to be more clinically effective. Since the ability of MAD's to reduce the AHI is more limited compared to CPAP, severe OSA patients are better served by CPAP. It is for this reason that MAD's cannot be considered as a disruptive innovation for the entire OSA patient population. Rather MAD's are seen suitable for mild and moderate OSA patients, as well as CPAP non-compliant patients. As a consequence, the strategic battlefield between the two technologies is the moderate patient group. The analysis shows a trend towards a better patient selection. CPAP providing companies are used to provide their 'one size fits all' devices to the majority of the patients. But if these CPAP providing companies still want to serve the broad OSA treatment market, they may need to diversify their treatment portfolios in order not to lose patients to newcomers who do offer these alternative solutions. Alternative treatments require better patients selections, because they are preferred in a more specific part of the OSA patients. A large CPAP company can invest in the diagnosis process, which can enlarge the entire OSA treatment market. Also, this provides better knowledge of tailoring the process of patient selection, which is beneficial if broadening their OSA treatment portfolio.

The value networks for CPAP and MAD are comparable in the higher-order levels of the value network. It is on the device level where the differences become most apparent. The treatment levels differ in the type of medical disciplines involved, but are structured in a comparable way. Notably, MAD value networks could have emerged outside a hospital setting and for example nested in a dentistry environment. The patient would in that case not visit the sleep centre at all. However, patients require a full sleep study and a treatment by a certified specialists, in order to get the treatment covered by health insurance. This health insurance requirement consequently drives the higher-ordered levels of MAD value network towards the sleep clinics.

The business system in case of a medical treatment was in this case study found to have specific characteristics, compared to other sectors on which a value network framework is applied. First, in health care, the decision making process is complex and involves multiple actors. The end consumer of a treatment – a patient – has influence on the type of treatment, but is not the main deciding actor, which are the medical specialists. They decide within the decision boundaries that are set by regulation and health insurers. Within OSA treatment, also different medical disciplines are involved in this process. The value network framework in combination with a care path analysis allowed for an understanding of this decision structure. Second, the supplier-customer relations differs in the higher levels of value network. Patients are not sold, but increase in health when referred to other specialists. Third, health insurance regulations may pull emerging value network towards the established one.

Any research implications for the theory of value networks and directions for future research are provided in the next chapter.

9. DISCUSSION

The results of the research are discussed in terms of the strategic implications, theoretical contribution and the quality and limitations of the findings and a possible agenda for future research.

9.1 DISCUSSION OF THE RESULTS

MAD seemed to have the classical characteristics of a disruptive innovation, but has not been identified as being one, when analyzing its disruptive potential along the measures of Christensen's (1997) theory of disruption. MAD shows limitations in treating the severe OSA patient group. Furthermore, as opposed to the examples provided by Christensen (1997), CPAP is not expected to increase in effectiveness, which does not enlarge the mismatch of demanded and supplied performance.

The analysis considers MAD patients as one patients group. One could argue that mild and severe patients should conceptually be divided in two separate types of patients. As a consequence, the relative importance of the values will change in this scenario. Within the severe patient group, the clinical effectiveness of the device will become increasingly important, leaving less space for MAD devices. In contrast, the mild OSA patient group may relatively value the comfort of MAD devices better than the high clinical effectiveness of the CPAP devices. Accordingly, one could even argue that mild patients are situated within a whole different value network than severe patients. This division into various patients groups was not made within this research for a number of reasons. First and most importantly, the set key performance attributes is still the same in both patient groups, only the relative importance differs. Furthermore, no patient is the same. In line with the argumentation of diversifying patients, one should also classify for example obese patients, since they may have a different prioritization of how they value performance attributes. It would conceptually be difficult to analyze moderate OSA patients, whereas the current outcome comprehensively includes all the patient groups.

After the pre-analysis within the academic literature, it was expected that MAD therapy, including the technology, is still in development. In line with that expectation, the MAD therapy was found to be a dynamic and developing therapy, albeit already commonly applied. The value network approach helped in further clarifying this. Surprisingly, when zooming in on the device level, it was found that the MAD devices itself (technology) is already mature, but the organization around MAD therapy, the diagnosis, the treatment process and MAD titration is not yet mature within the Dutch health system. In contrast with the expectations, it was found that GP referrals were found to be influenced by regional factors such as local agreements between GPs and hospitals, or hospitals and dentists.

9.2 THE VALUE NETWORK APPROACH

The value network had hardly been used in previous literature on entrant-incumbent dynamics (Sandström, 2010). The framework was found to be a comprehensive tool in this study. First, the value network framework was found useful in the identification of the potential of an emerging technological trajectory to replace an existing ones. It could be assessed whether the value network for the emerging technology (MAD) emerged within the value network of the incumbent, or next to it. By using its multi-layered approach, it became clear on which system level the value networks differed. Second, this multi-level approach led to strategic implications for incumbent firms on how to position in the competition *between* technologies (treatment option

level) and *within* one technology (device level). Third, the identification of 'key performance attributes' within each system level was found to be a useful way to understand where competition is based on in each part of the value network. Fourth, the framework was found useful in an assessment of a multi-decision structure that can be seen in healthcare, although the role of insurers and patients in this multi-decision structure can be further developed in future research. Within this research, there was a clear emphasis on the treatment of OSA, because MAD is an OSA treatment option. In addition to the treatment focus as was chosen in this research, it would be useful use a 'diagnosis' level, ordered horizontally next to the treatment options level. The diagnosis also consists out of a process and devices that involve a value creating business system. Together with the treatment value networks, this provides a more comprehensive understanding of the value networks around one disease.

This study contributed to the research on innovation in health care by applying a new approach of understanding the complex and multi-layered nature of competition between treatment options and medical devices. This thesis shows that the value network framework can be used in complex heath care innovations. In doing so, a care path analysis was added in order to analyze the context and decision making actors. The care path analysis was found to be a helpful tool for the identification of the context in which OSA treatment takes place, as well as the important decision making actors involved. The type of business relations in the higher-order levels differ in nature from other industries where the value network approach is applied. In particular, the type of customer – supplier relations differs in the higher-ordered levels. Patients are not sold to other actors in the system, but increase in health when referred to other specialists. Moreover, it was found that health insurance requirements, can drives the higher-ordered levels of MAD value network towards hospitals, leaving little space for entering technologies to develop value networks next to the one of the established treatment. Regulation and health coverage pull the new emerging value networks into the existing one. This may be an indication for a difficulty in achieving disruptive innovation in health care.

The value network approach differs in its focus from the more commonly applied method of health technology assessments (HTA) for the evaluation of health care technologies. HTA's were originally defined as a "*comprehensive form of policy research that examines the short- and long-term social consequences of the application or use of technology*" (Banta, 2002, p. 123), but HTA has grown into a broad concept which can differ from country to country (Banta, 2002). HTA's focuses on the safety, quality, efficacy, effectiveness and cost/benefit of health care technologies. This provides valuable knowledge for policy makers, insurers, physicians, researchers, industry and the general public (Banta, 2002), often a priori before the technology is on the market. The value network shows the entire context in which companies compete - as in this research delineated by the care path - the main values on which different technologies compete and how this translates into technological aspects on which similar devices compete.

9.3 Limitations and Quality of the Research

The data sample contains a wide range of medical specialists involved in OSA diagnosis and treatment, including a representative of the patient's organization and a MAD producer. Because of the exploratory character of the research, the findings were not statically validated among a larger group of respondents.

The data sample focused on the medical specialists, because they were expected to be the decision making actors. However, the role of the patients and the insurance companies was also found to be important. This was partly covered by an interview with the patients' association's representative and the information provided by the medical specialists, who gave a lot of information on patients' decisions and health insurance company involvement. However, including interviews with patients and insurance companies would have enriched the results. The broad selection of respondents over the OSA care path provided representative and complete picture of OSA diagnosis and treatment in the Netherlands. This was also indicated by the last five conducted interviews that provided little new information. This can be an indication of interview saturation. The data set was limited to the Netherlands. Key performance attributes in care paths and value networks may be different in other countries. Because of the large influence of cultural factors, policy factors and insurance coverage that are typical for the Netherlands, the results cannot be generalized to OSA treatment in other countries.

In order to enrich the understanding of CPAP versus MAD competition, questionnaires were sent to stakeholders within a large CPAP producing company. Unfortunately, there was zero response. Performance attributes in the CPAP device level could largely be covered by the pulmonologists, OSA nurses and neurologists interviews. When studying the role of incumbents, other data sources may be more fruitful in future research, including historic analysis of company data and observations within the company.

In order to ensure traceable findings, a careful documentation of the analysis process has been made. All the claims in the findings part of the result section refer to the interview data. The interviews conducted were transcribed verbatim in order not to dilute the data before it was analyzed. The interview transcripts and interview audio is available on request. Furthermore, the coding schemes allow for tracing the claims from the findings sections. Additional reliability issues have been discussed in the methodology chapter.

Although the desk top study provides a lot of insightful information, its results should be treated with caution. Information on a sleep clinic's website may be outdated or not representative for the actual processes within the clinic. The analysis considering the number of referrals differs between the analysis and the report by the Dutch Apneuvereniging (2012). This can be explained by the fact that not all clinics reported this on their website; the used sample is likely to differ. Furthermore, the Apneuvereniging (2012) used a more qualitative approach, which can be more reliable than data on the website of the clinic as previously discussed. The report by the Apneuvereniging (2012) covered not all the issues discussed in the desk study and can therefore be seen as complementary.

9.4 Further Research

In line with the findings concerning a demand for better diagnosis methods, more research is needed on current diagnosis methods and ways to improve this. The value networks of CPAP and MAD have been identified for the Dutch situation. Further research is needed to understand the competition of these technologies in a broader sense. This can be achieved by researching this competition in other countries. This will also provide insights on the role of regulation and incentives created by health insurers.

Furthermore, the role of insurers may be researched in more detail in order to better understand the multi-actor decision structures.

More research on value networks in health care will contribute to a better understanding of the dynamics in emerging innovation in health care. In applying the value network in OSA treatment, this research identified a number of characteristics in health care, including its multi-actor decision making, a-typical supplier-customer dynamics and regulation pulling an emerging value network towards the established one. When applying the value network approach in combination with care path analysis on more diseases next to OSA and more, it can be assessed to which extent these characteristics can be generalized. Furthermore, the dynamics within emerging value networks are likely to be country specific. When applied in different countries, it can be assessed which factors are country specific and which are general characteristics of value networks in health care. Besides, historic analysis of the development of emerging value networks in health care is needed to gain a better understanding of the development of the value networks over time.

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Figure 2.2 – An edit of the picture on page 863 in: Sullivan, C., Berthon-Jones, M., Issa, F., Eves, L., 1981. Reversal of obstructive sleep apnoea by continuous positive airway pressure applied through the nares. The Lancet 1, 862–865.

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Figure 3.2 – Picture based on (Christensen ,1997, p xvi): Christensen, C.M., 1997. The innovator's dilemma: when new technologies cause great firms to fail. Harvard Business School Press, Boston.

Figure 5.2 – (All retrieved on June 17th 2013)
**Top Left*: SomnoMed (2013), retrieved from http://www.somnomed.com/Products/SomnoDent.
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**Bottom Right*: Excent (2013). Retrieved from: http://www.excent.eu/voor-tandartsen/producten/orthodontie/mra/easy-comfort-mra/.

Figure 3.3, 5.1, 6.1-6.5, 7.1 and 8.1 – Created by the author (Daniël Doorman) throughout the research (februari – juli 2013).

APPENDIX A – DESK RESEARCH ANALYSIS

The data of the desk research was analyzed by using Microsoft Excel. Each sleep clinic was filled in on a new row, containing the city (column A), the clinic's name (column B), the number of patient intakes per year (column C), the specialist responsible for the intake (column D), the presence of an ENT, pulmonologist, neurologist, OMS, OSA nurse, Psychologist, Dentist or other specialist (column E - L), if they perform MAD (column M) and who performs the MAD treatment (column N). Figure B.2 shows a phrase of the table. The full table is presented in Appendix B. In case a specialist was present within the clinic, a 'X' was filled in. In case the specialist worked part-time in the clinic, an S was filled in. In case there was nothing stated about the presence of a specialist nothing was filled in. The cells were auto-colored (X=blue, S=orange). Consequently, the percentages of overall present specialists were calculated as a percentage of the total number of clinics. In the case of ENTs (column E), this was done with the following formula *(the total number in-clinic ENTs + total number of part-time ENTs) / total number of clinics*):

"=(COUNTIF(E2:E82;"x")+COUNTIF(E2:E82;"s"))/81"

The same formula was applied for the other specialists, using their specific column. The same formula was also applied to calculate the other percentages concerning MAD treatment and intakes in which X was substituted by the name of the specialist. For instance, the number of intakes by the pulmonologists responsible for the intake was thus calculated with the formula:

"=(COUNTIF($D$2:$D$82;"pul"))/81".

Table B.1 *- legenda*

Label	**Explanation**	
City	City within Holland	
Clinic/Hospital	Name or the hospital	
# pat*j-1	Number of patients per year that undergo a sleep study.	
	–	
Intake	The specialist to which the GP send patients, according to the hospital's website.	
	Label	**Explanation**
	Pul	Pulmonologist is the first who sees the patient
	ENT	Ear, Nose and Throat specialist takes care of the intake
	Neur	Neurologists is the first who sees the patient
	ENT/Pul	Both a ENT and Pul are named, but no further specifications
	E/P/N	ENT, Pulmonologist or Neurologists. The GP decides where to go to first based on the guidelines. Thereafter, the specialists may redirect: • ENT: When snoring is the major problem • Pulmonologist: When suspecting OSA or related disorders • Neurologist: When suspecting other or complex disorders.
	Gen.	General intake. Sleep centre decides to which specialists the patient goes.
	OSA verpl	A special sleep (OSA) specialist does the intake and decides who to see next
	ALL	The patients visits all the specialists (ENT, Pul and Neur)
Practitioners present in the hospital		
x	Present within Clinic/Hospital	

s	Cooperation with / part time in sleep clinic	
	ENT	Ear, Nose and Throat specialist
	Pul	Pulmonologist
	Neu	Neurologists
	OMS	Oral and Maxillofacial Surgeon
	OSA	Special OSA nurse / practitioner
	Psy	psychologist / Psychiatric
	D/O	Dentist or Orthodontist
	Other	Other. May include (obesity) therapist, child doctor or medical (laboratory) analyst
MRA	MAD is preformed within the hospital (x), by a external party outside the hospital (s), or not mentioned on the website (n.m.). In some cases, the websites mention the possibility of mra, but there is no further specification (a).	
Who	The specialist responsible for the MAD therapy	

Table B.2 - first 12 sleep out of 81 sleep clinics

City	Clinic/hospital	# pat*j^{-1}	Intake	ENT	Pul	Neu	OMS	OSA	psy	D/O	Other	MAD	Who
Den Haag	Medisch Centrum Haaglanden	2300			x	x		x	x		x	x	D/O
Utrecht	St. Antonius Slaapcentrum - locatie Nieuwegein/Utrecht en Overvecht	1700	Gen.	x	x	x	x	x	x	x		x	
Eindhoven	Catharina Ziekenhuis	1000	Pul	x	x	x						x	
Ede	Ziekenhuis Gelderse Vallei	900		x	x	x	x	x		x	x	x	OMS
Roermond	Laurentius Ziekenhuis	800	ENT/ Pul	x	x	x	x					x	
Scheidam	Vlietland Ziekenhuis	789	Gen.	x		x		x				x	EC
Rotterdam	Sint Franciscus Gasthuis	650	Gen.	x	x	x	x	x	x	x		x	D/O
Rotterdam	Maasstad Ziekenhuis,	600	OSA verpl.	x	x	x	x					x	
Den Haag	Bronovo Ziekenhuis	500	ENT	x	x	x	x	x		x		x	D/O
Leeuwarden	Medisch Centrum Leeuwarden	500	Pul	x	x	x	x					x	OMS
Woerden	Zuwe Hofpoort Ziekenhuis, Instituut voor Slaapgeneeskunde	500	ENT/ Pul	x	x	s	x					x	OMS
Zaandam	Slaapcentrum Zaans Medisch Centrum	400	E/P/N	x	x	x	s		x			x	OMS

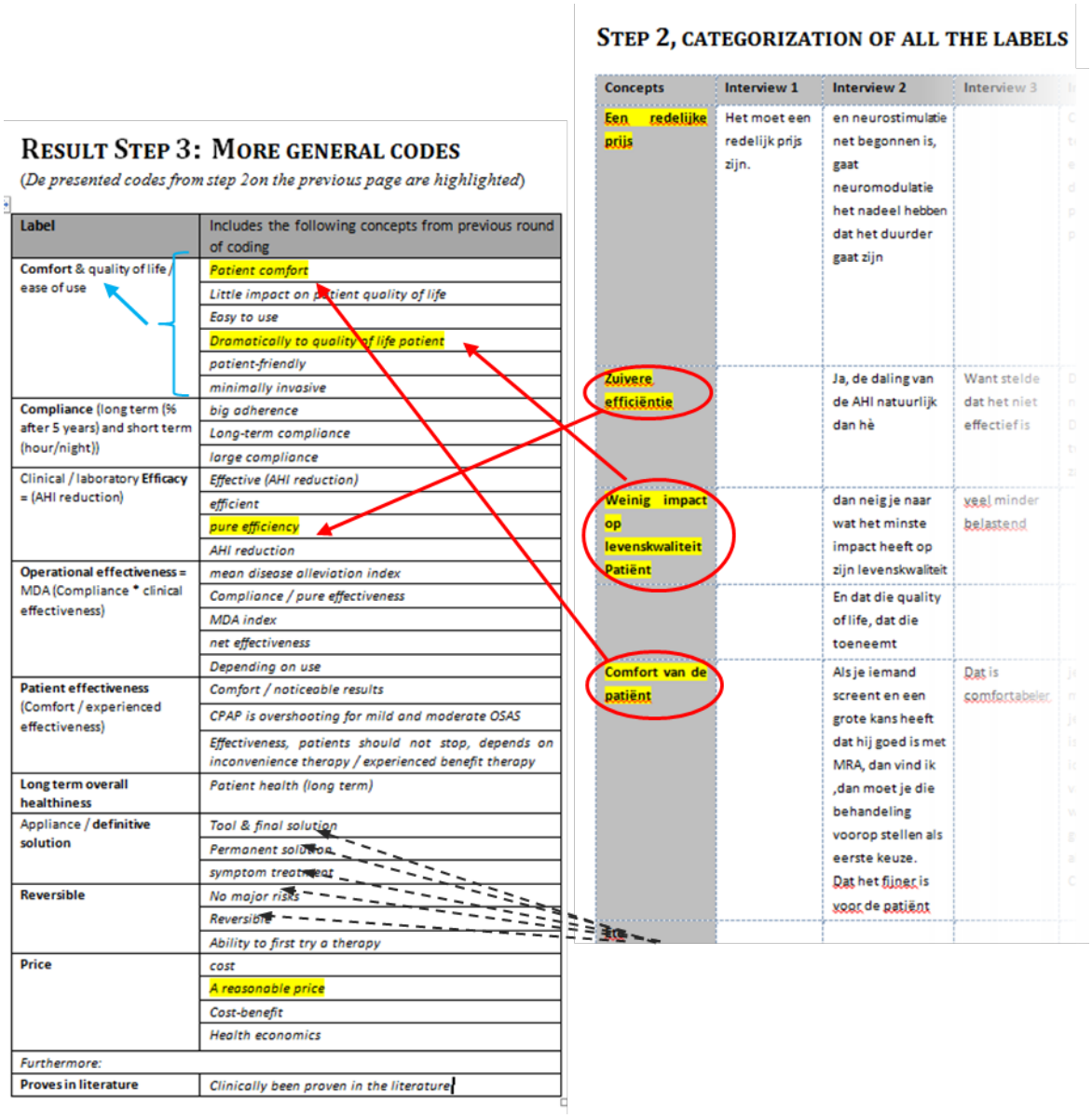
This table shows a part of the file that was used in the desk research on the 82 sleep clinics.

Appendix B, Coding Strategy Expert Interviews Code Determination

An explanation is provided in the methodology section in the main text.

The table of step 2 contains codes from the text. It is seen that the codes from step two are used to create more abstract and general codes for step three.

Explanation step 2 to step 3



Result Step 3: More general codes

(De presented codes from step 2on the previous page are highlighted)

Label	Includes the following concepts from previous round of coding
Comfort & quality of life / ease of use	*Patient comfort*
	Little impact on patient quality of life
	Easy to use
	Dramatically to quality of life patient
	patient-friendly
	minimally invasive
Compliance (long term (% after 5 years) and short term (hour/night))	*big adherence*
	Long-term compliance
	large compliance
Clinical / laboratory **Efficacy** = (AHI reduction)	*Effective (AHI reduction)*
	efficient
	pure efficiency
	AHI reduction
Operational effectiveness = MDA (Compliance * clinical effectiveness)	*mean disease alleviation index*
	Compliance / pure effectiveness
	MDA index
	net effectiveness
	Depending on use
Patient effectiveness (Comfort / experienced effectiveness)	*Comfort / noticeable results*
	CPAP is overshooting for mild and moderate OSAS
	Effectiveness, patients should not stop, depends on inconvenience therapy / experienced benefit therapy
Long term overall healthiness	*Patient health (long term)*
Appliance / **definitive solution**	*Tool & final solution*
	Permanent solution
	symptom treatment
Reversible	*No major risks*
	Reversible
	Ability to first try a therapy
Price	*cost*
	A reasonable price
	Cost-benefit
	Health economics
Furthermore:	
Proves in literature	*Clinically been proven in the literature*

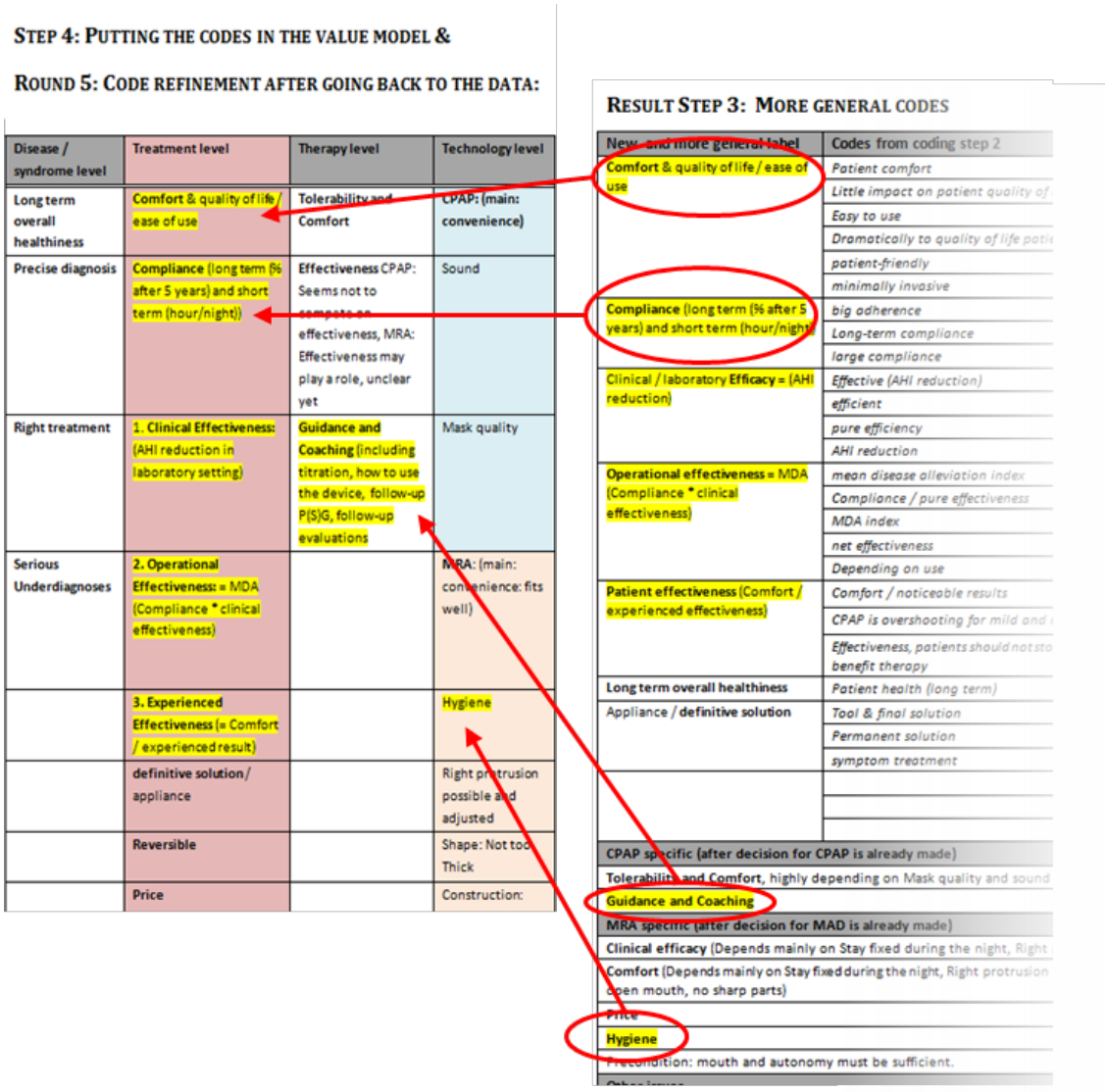
Step 2, categorization of all the labels

Concepts	Interview 1	Interview 2	Interview 3
Een redelijke prijs	Het moet een redelijk prijs zijn.	en neurostimulatie net begonnen is, gaat neuromodulatie het nadeel hebben dat het duurder gaat zijn	
Zuivere efficiëntie		Ja, de daling van de AHI natuurlijk dan hè	Want stelde dat het niet effectief is
Weinig impact op levenskwaliteit Patiënt		dan neig je naar wat het minste impact heeft op zijn levenskwaliteit	veel minder belastend
		En dat die quality of life, dat die toeneemt	
Comfort van de patiënt		Als je iemand screent en een grote kans heeft dat hij goed is met MRA, dan vind ik ,dan moet je die behandeling voorop stellen als eerste keuze. Dat het fijner is voor de patiënt	Dat is comfortabeler

Step 4: Putting the codes in the value model &

Round 5: Code refinement after going back to the data:

Here an example is provided of how the codes in step three were put into the value network model.



STEP 4: PUTTING THE CODES IN THE VALUE MODEL &

ROUND 5: CODE REFINEMENT AFTER GOING BACK TO THE DATA:

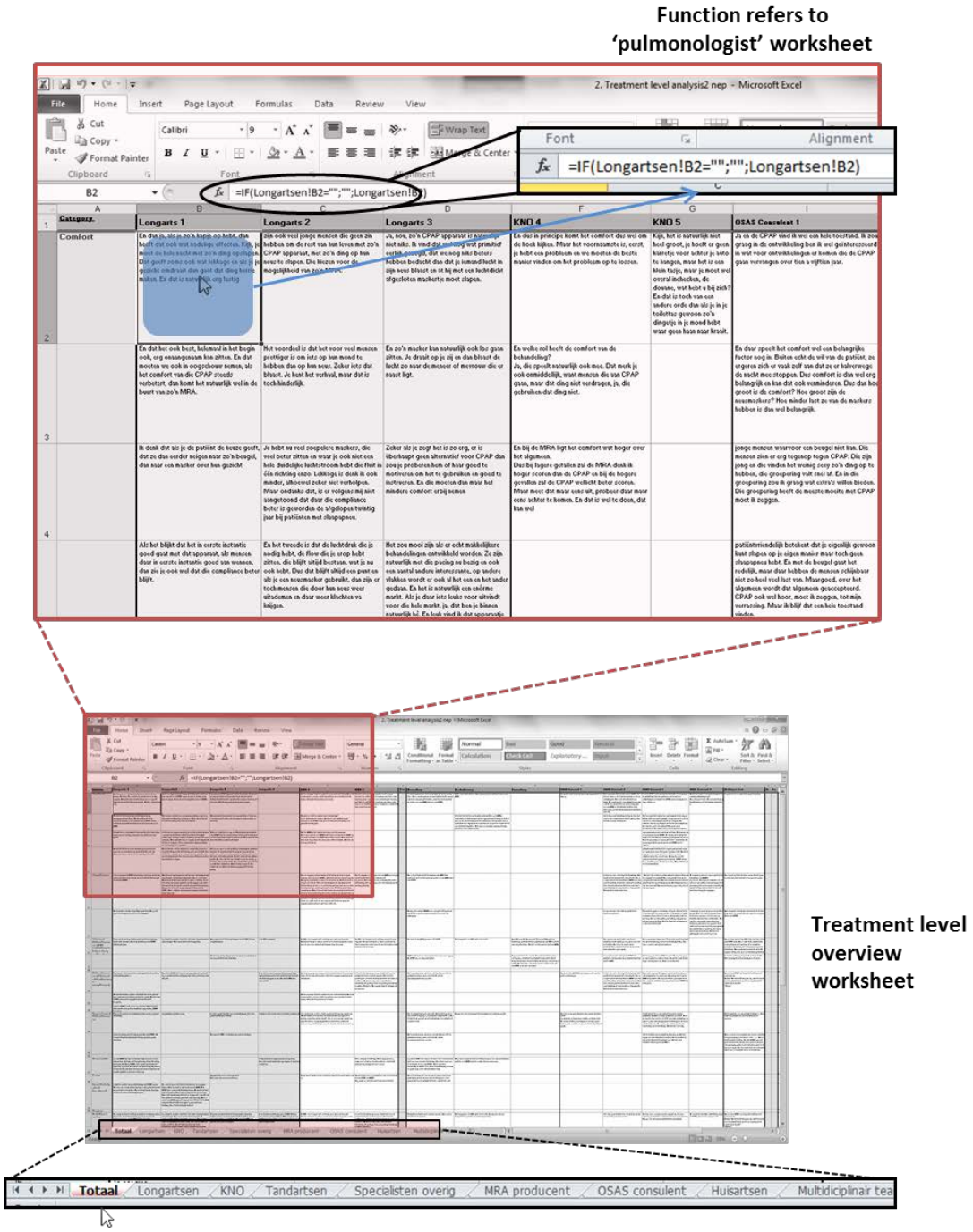
Disease / syndrome level	Treatment level	Therapy level	Technology level
Long term overall healthiness	Comfort & quality of life / ease of use	Tolerability and Comfort	CPAP: (main: convenience)
Precise diagnosis	Compliance (long term (% after 5 years) and short term (hour/night))	Effectiveness CPAP: Seems not to compete on effectiveness, MRA: Effectiveness may play a role, unclear yet	Sound
Right treatment	1. Clinical Effectiveness: (AHI reduction in laboratory setting)	Guidance and Coaching (including titration, how to use the device, follow-up P[S]G, follow-up evaluations	Mask quality
Serious Underdiagnoses	2. Operational Effectiveness: = MDA (Compliance * clinical effectiveness)		MRA: (main: convenience: fits well)
	3. Experienced Effectiveness (= Comfort / experienced result)		Hygiene
	definitive solution / appliance		Right protrusion possible and adjusted
	Reversible		Shape: Not too Thick
	Price		Construction:

RESULT STEP 3: MORE GENERAL CODES

New, and more general label	Codes from coding step 2
Comfort & quality of life / ease of use	*Patient comfort*
	Little impact on patient quality of
	Easy to use
	Dramatically to quality of life pati
	patient-friendly
	minimally invasive
Compliance (long term (% after 5 years) and short term (hour/night)	*big adherence*
	Long-term compliance
	large compliance
Clinical / laboratory Efficacy = (AHI reduction)	*Effective (AHI reduction)*
	efficient
	pure efficiency
	AHI reduction
Operational effectiveness = MDA (Compliance * clinical effectiveness)	*mean disease alleviation index*
	Compliance / pure effectiveness
	MDA index
	net effectiveness
	Depending on use
Patient effectiveness (Comfort / experienced effectiveness)	*Comfort / noticeable results*
	CPAP is overshooting for mild and
	Effectiveness, patients should not sto benefit therapy
Long term overall healthiness	*Patient health (long term)*
Appliance / definitive solution	*Tool & final solution*
	Permanent solution
	symptom treatment
CPAP specific (after decision for CPAP is already made)	
Tolerability and Comfort, highly depending on Mask quality and sound	
Guidance and Coaching	
MRA specific (after decision for MAD is already made)	
Clinical efficacy (Depends mainly on Stay fixed during the night, Right	
Comfort (Depends mainly on Stay fixed during the night, Right protrusion open mouth, no sharp parts)	
Price	
Hygiene	
Precondition: mouth and autonomy must be sufficient.	

Shown: 4 out of 19 interviews, only the treatment level, only the first 3 pages out of 3.

Round 7: Integration and refinement
(1/4 of the treatment level Excel File)



Final codes

Overall OSA level	Treatment options level	Treatment level	Tech. Level CPAP	Tech. Level MAD
Long term overall healthiness	**Comfort**	Guidance and Coaching	**Comfort:**	**Comfort:**
Serious Underdiagnoses	**Compliance**	Habituate (wenperiode)	*Sound*	*Adjustible*
Precise / other diagnosis required	**Clinical Effectiveness** (AHI reduction)	Keep therapy at the specialists	*Design*	*Good material*
Knowledge about OSA	True effectiveness*	Holistic therapy: Weight reduction	*Size*	*Hygienne*
Insurance	**Experienced Effectiveness**	Service MAD / CPAP supplier	*Mask quality*	*Longer term inconveinience*
Multidiciplinairity	*Reversible*	Path dependency in working with supplier	Types of PAP	Power Distribution over teeth
	Price		Readout	Readout
Care path:	*Immediately start treatment*		Effectiveness	Mature technology
GP referral	*Proven technology*		Mature technology	Price
Specialist intake & treatment	*Anatomy factors*		Price	warranty
Path dependency	*Proves in literature*			Effectiveness
Care path MAD	*Severity level*			
	Clinical guidelines			

*Later added

References to interview transcripts as used in the main text

Interview number	Respondent	Interview number	Respondent
IV 1	Expert 1 (ENT 1)	IV 13	Dentist 3
IV2	Expert 2 (Dentist 1)	IV 14	Neurologist
IV 3	Expert 3 (ENT 2)	IV 15	OMS
IV 4	Expert 4 (ENT 3)	IV 16	Somnologist
IV 5	Expert 5 (Patients' association)	IV 17	MAD producer
IV 6	Pulmonologist 1	IV 18	OSA nurse 1
IV 7	Pulmonologist 2	IV 19	OSA nurse 2
IV 8	Pulmonologist 3	IV 20	OSA nurse 3
IV 9	Pulmonologist 4	IV 21	OSA nurse 4
IV 10	ENT 4	IV 22	Multidisciplinary team consultation
IV 11	ENT 5	IV 23	GP 1
IV 12	Dentist 2	IV 24	GP2

APPENDIX C QUESTIONNAIRES

Vragenlijst Interview Expertinterviews

Korte introductie van de studie SIM & afstudeertraject naar slaapapneu. Mogelijkheid anoniem te blijven. Mag het worden opgenomen?

- Hoe zou de ideale behandelmethode voor obstructieve slaap apneu eruit zien?
- Op welke manier wordt een beslissing gemaakt voor een behandelmethode?
- Wat zijn belangrijke aspecten van een OSA behandeling?
- Het is mogelijk om CPAP en MRA te zien als twee oplossingen voor hetzelfde probleem. Ziet u deze twee behandelmethode als concurrenten van elkaar?
- Welke rol ziet u weggelegd voor bedrijven binnen een MRA behandeling?
- Wat is de rol van nieuwe technologie binnen de verschillende behandelingen van OSA?

- *Zijn er nog andere zaken die u de moeite waard lijken te vertellen binnen dit onderzoek?*
- *Weet u andere specialisten die ik zou kunnen benaderen voor een interview?*

Hartelijk dank voor het interview. Indien u nog vragen heeft kunt u contact met mij opnemen. Contactgegevens geven.

Possible follow ups

Questions	Possible follow-ups
Introduction question: within our master program we study innovation.	
How does an ideal OSA treatment looks like?	What aspects are missing whting the current treatment methods?
How do you decide for a treatment for a diagnosed OSA patient?	Different decision moments. Role of clinical guidelines.
What are important aspects within an OSA treatment?	- Effectiveness (in AHI) - Experienced effectiveness - Compliance - Comfort - Costs - Safety
Do you consider CPAP and MAD as two different solutions for the same problem? Do you see CPAP and MRA as two competitors?	In what case which treatment? Do the different care paths of CPAP and OSA differ, or are they similar?
How do you consider the role of companies within a MAD treatment?	Performing in: - Research - Production - Tailoring - Titration - Checkups
What is the role of technology within different OSA treatments?	Role of technological change?

Stakeholder interviews, operationalization

Level	Values	Questions
Treatment options level What values play a key role in the valuation of a treatment option?	All	What do you consider as characteristics of a good OSA treatment?
		Which aspects do you miss in the current treatments?
		How do you decide for a treatment for a diagnosed OSA patient?
	Comfort	How do patients experience the different OSA treatments?
	Compliance	What is the role of compliance within an OSA treatment?
	Effectiveness	What makes an OSA therapy effective? *{AHI; Comp * AHI?; comf* comp?}*
	Other factors	What other factors play a role in an OSA treatment?
	Relative relevance (and relation between)	How do compliance and effectiveness of a therapy relate to each other?
		What discussed factors (effectiveness, comfort, compliance, etc) do you consider very important in an OSA treatment?
		Which of the discussed factors do you consider as less important?
		To what extend are the discussed factors patient specific?
And in combination with different patient groups	All	What are decisive factors in case you doubt between CPAP and MAD?
	Severe OSA	What discussed factors (effectiveness, comfort, compliance, etc) do you consider as most important in the case of severe OSA?
	Mild OSA	What factors do you consider as most important in the case of mild OSA?
	Moderate OSA	What factors do you consider as most important in the case of mod. OSA?
	Other factors	What other situations or patient characteristics influence the relative importance of those factors?
Treatment & technology level MAD specific	What are characteristics of a good MAD therapy?	
	Which of these factors play the most important role in choosing between different types of MAD?	
	What is the role of commercial companies in MAD?	
	How can you explain the increase of MAD devices the last years?	
	How does the referral process to a MAD provider looks like? How is the decision for a certain center being made? And how is the collaboration with these centers?	
CPAP specific	What are characteristics of a good CPAP therapy?	
	Which of these factors play an important role in choosing between different types of CPAP?	
	What is the role of coaching and guidance in the CPAP therapy?	
Are CPAP en MAD competing technologies?	Are there situations in which you would definitely choose for MAD over CPAP? If yes, when?	
	Do you consider CPAP and MAD as two different solutions for the same problem?	
	To what extent do you consider CPAP and MAD as two competing therapies/technologies?	
Anything more you like to add?		

Vragenlijst stakeholderinterviews

Introductie door Daniël (Opleiding SIM, onderwerp, doel, anoniem verwerkt, inzicht in transcript mogelijk)

- Hoe komt u tot behandeling voor een gediagnostiseerde OSA patiënt?
- Wat zijn eigenschappen van een goede OSA behandeling?
    - Zijn er aspecten die u mist in de huidige behandelopties?
    - Hoe ervaren patiënten de verschillende behandelmethodes?
    - Welke rol heeft compliance binnen een OSA behandeling?
    - Wat maakt een OSA behandeling effectief?
    - Zijn er naast compliance en effectiviteit nog andere factoren die een rol spelen in de keuze voor een bepaalde behandelmethode?
    - Hoe verhouden de compliance en de effectiviteit van een behandeling zich tot elkaar?
- Er zijn zojuist enkele factoren besproken die invloed hebben op de keuze voor een bepaalde behandelmethode. Welke hiervan wegen extra zwaar in uw keuze?
    - Welke wegen juist minder zwaar?
    - In hoeverre hangt dit af van de specifieke situatie van een patiënt?
    - Welke van de besproken factoren (zoals effectiviteit en compliance) zijn vooral van belang bij patiënten met ernstige OSAS?
    - En hoe is dat bij milde of matige OSAS?
- Hoe ziet het proces eruit waarop patiënten worden geselecteerd voor MRA?

Nu komen enkele vragen iets specifieker over MRA en CPAP

- Wat zijn eigenschappen van een goede MRA?
    - Welke aspecten kijkt u naar bij het kiezen van een bepaald type MRA?
    - Wat is de rol van commerciële bedrijven bij een MRA behandeling?
    - Ziet u een toename in het gebruik van MRA apparaten? Zo ja, kunt u verklaren waarom het aantal MRA behandelingen zo is gegroeid afgelopen jaren?
- Hoe werkt het verwijzingsproces rondom een MRA behandeling? Hoe wordt de keuze gemaakt om door te verwijzen naar een bepaald centrum en hoe is de samenwerking met deze centra?
- Wat zijn eigenschappen van een goede CPAP behandeling?
    - Waar kijkt u naar bij het kiezen van een CPAP apparaat?
- Zijn er gevallen waarin u zonder twijfel kiest voor een CPAP- of juist een MRA behandeling?
    - Wat is doorslaggevend als u twijfelt tussen een CPAP en een MRA?
    - Ziet u CPAP en MRA als twee oplossingen voor hetzelfde probleem?

Bedankt! Zijn er nog andere dingen die u hierover kwijt wilt? Wat vond u van het interview?