UPPSALA
UNIVERSITET

Företagsekonomiska institutionen
Department of Business Studies

Drivers and Hindrances to Med-Tech Innovation

A device's guide to the Swedish healthcare galaxy

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Dissertation presented at Uppsala University to be publicly examined in Hörsal 2, Kyrkogårdsgatan 10, ppsala, Monday, 12 June 2017 at 13:15 for the degree of Doctor of Philosophy. The examination will be conducted in Swedish. Faculty examiner: Professor Björn Axelsson (Handelshögskolan, Stockholm).

Abstract
Wagrell, S. 2017. Drivers and Hindrances to Med-Tech Innovation. A device's guide to the Swedish healthcare galaxy. *Doctoral thesis / Företagsekonomiska institutionen, Uppsala universitet* 186. 251 pp. Uppsala: Företagsekonomiska institutionen, Uppsala universitet. ISBN 978-91-506-2639-1.

Today, the expectations on new medical technology solutions are substantial. On the one hand, healthcare policy expects new technologies both to improve the quality of people's life and to reduce the burgeoning healthcare costs. On the other hand, innovation policy expects new med-tech solutions to stimulate *economic growth,* with large emphasis on the *production* of new solutions. However, despite the growing importance of med-tech innovations it is cumbersome to embed these innovative promising products into use in the Swedish healthcare sector.

This thesis investigates med-tech innovation by following a microwave-based device in the treatment of the common disease BPH, *Benign Prostatic Enlargement*. This is an empirically based longitudinal study where the microwave device is used as a probe to capture a med-tech innovation journey. We follow the device through the efforts of technological and scientific development, through complex industrial production structures and foremost inits struggles to achieve widespread use in Swedish public healthcare.

This study identifies a number of hindrances and drivers and, importantly, how they are interconnected in the innovation process. By applying the different settings of *development, production and use* of this device, a central finding is that the very same mechanisms can have contradicting effects in the different settings. Moreover, what functions as a trigger to innovation during development, can become later a hindrance to use. The study also shows that, whereas drivers prevail over hindrances in the development and production of med-tech solutions, hindrances clearly prevail in their use, which involves the provision of healthcare services. Not only has the use setting a generally weak financial support, but its organisational structures and regulations do also have a negative impact on the spread of new solutions in healthcare.

Keywords: med-tech, innovation, healthcare, resource interaction, industrial networks

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ISSN 1103-8454
ISBN 978-91-506-2639-1
urn:nbn:se:uu:diva-320673 (http://urn.kb.se/resolve?urn=urn:nbn:se:uu:diva-320673)

To Enzo & Astrid

ACKNOWLEDGEMENTS

It feels fantastic to actually be about to finish years of work on this project. Most of all I am grateful for having had the opportunity to acquire knowledge that can be applied in a more universal sense, something which have had an impact on how I comprehend the world and which stretches beyond research. The theoretical stances for this thesis is by many means universal, in the ways it acknowledges that there is nothing able to occur in isolation, something that holds true also for this piece of research.

To my supervisors: Alexandra, I would never have initiated this journey if it weren't for you. I think you convinced me somewhere between Park Towers and Palo Alto Café. You have believed in me and this project from day one and been a great source of inspiration, always contributing with sharp and creative comments. My greatest gratitude to you. A sincere thankyou also to Per-Ingvar for patient reading of my texts and your insightful comments along the way.

I would also specifically like to thank, Thomas Hoholm and Johnny Lind for their very valuable comments on this manuscript during my final seminars and to Håkan Håkansson for reading various texts over the years, always providing insightful comments.

To my closest colleagues: Malena, you are my dear friend and I can't thank you enough for making academic life be about something more than 'just research', which I seriously needed. Indeed, we had long days of doing research at the office, discussing, reading and perhaps most of all brainwork: we have been thinking a lot! However, we have also danced many nights away together, those were the happy days and I hope there will be many more to come. That goes for, Åse, Anna Ljung and Anna Launberg, as well.

I am also deeply grateful to all the respondents who have participated in this study. Without you giving me the opportunity to do interviews and visit your clinics/departments, hospitals and companies, I could not have undertaken this study in the first place. I sincerely appreciate your engagement.

However, writing a thesis was not only an entertainment trip down happy-lane. It was indeed great fun, some of the time. Yet we had our moments, me and my thesis. At times, research tends to crawl under your skin and there are

moments when you simply have to move into an ‘alternative reality’ and create a monogamous relationship with your thesis (think “my precious”). Meanwhile you’re *inside* that ‘maverick-world’ –living in horryfying delight obsessed with your text, and then, when you *return* from it, to face reality again, it is essential to have a well-functioning ‘ground service’– spells family.

First of all, the greatest of gratitude to my fantastic children, Enzo and Astrid, and husband Enrico. For being amazing and putting up with me in my most neurotic moments, for dragging me from the computer when I surely had become ‘text-destructive’ anyways and for making me laugh and continue writing, when I was willing to take any practically oriented work offered to me on the face of Earth. Enrico, you have been a rocksteady support at all possible levels (which husband brings you champagne and flowers on a Monday to cheer you up?) – grazie amore, sei fantastico!

I am also grateful to my father for first introducing me to the ‘golden world of urology’ and for the support and the many important discussions we have had over the years. And then a big thankyou to my mother for your firm believe in me and your patience in listening to my endless discussions on innovation and healthcare policy – without even yawning once, however asking questions every other second. That is a true accomplishment, on all levels. Thank you. To my bonus parents, who have been there with me since early childhood and always been cheering on me, Birgitta and Mats, you are the best!

And then you, my dear sisters, there are so many of you, which is a true blessing. You have taken care of my children, made Tuesday-dinner parties at rainy October nights, told me totally insane jokes with your very particular sense of humour, the list goes on and on. I am so grateful. Johanna, Ida, Kristin, Elin, Charlotta, thank you, you mean the world to me. Thank you also to the bonus family members, Catarina, Anna and Charlotte.

Family, know that you all have worked your miracles when I needed it the most.

Last, I would like to express my gratitude to Handelsbanken Research Foundation and Handelsrådet for financial support of this thesis.

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"*Men with benign prostatic hyperplasia must be given access to relevant care. Today's urology care, displace this group of patients, leading to irreversible damage and unnecessary suffering of many patients and costly care.* [...] *New ways should be sought to meet the patients' legitimate demands for curative treatment. I have operated a thousand patients with prostate planing (TURP). My experience of treating with TUMT is a hundred cases, and I have not seen any serious side effects. The heat treatment is nowadays both fast (generally less than 15 minutes) and substantially painless*."

Journal of the Swedish medical association (*Läkartidningen*) 2017, p.534-535 (Authors translation)

1. A NEW MED-TECH INNOVATION IN THE TREATMENT OF BENIGN PROSTATIC ENLARGEMENT

More or less all men will experience inconveniences caused by an enlarged prostate, commonly when past the age of 50. As many as 50% of all men will need treatment for these problems (Blandy, 1971; Barry, 1990). Benign enlargement of the prostate, BPH, implies a *benign growth* of the prostate gland and, under normal circumstances, is not a fatal condition. Nevertheless, it is a common disease affecting a significant amount of the male population, thus causing high expenditures to the healthcare system.

The gold standard procedure for active treatment of BPH is the endoscopic surgical procedure, TURP, *Trans Urethral Resection of the Prostate*. This surgical procedure involves the common implications of surgery; hospitalisation, aftercare, sick-leave and the patients have to be under general anaesthesia. Another cumbersome issue with BPH treatment is that patients commonly are older (almost all are over 50 years of age and the majority are over 70), which implies that the risks with surgery and general anaesthesia are high. Some of the oldest patients are simply too weak or vulnerable to undergo surgery. However, in the early 1990s, a new medical technology solution named TUMT was introduced in the Swedish healthcare system. TUMT is the abbreviation for *Trans Urethral Micro Thermotherapy* and is a microwave-based med-tech invention offering an alternative to traditional surgery. This minimally invasive treatment method was made available through a small Swedish medical technology producer, *ProstaLund,* which developed the device in cooperation with a urology clinic at a medium-sized Swedish hospital. Not only did this machine offer an alternative treatment option for the many old men suffering from prostate problems that were unable to undergo surgery, but it was also claimed to be cost-efficient since no surgery, lengthy hospitalisation or general anaesthesia was needed, given that after the procedure, the patients were able to leave the hospital the same day.

Consequently, in the early 1990s, BPH treatment potentially stood before a grand change; far fewer surgical procedures, as possibly almost all patients could be treated with minor complications and at much lower costs. New technologies were supposed to rationalise otherwise expensive treatment methods in a Swedish healthcare system often accused of being both outdated and rigid.

*

This thesis will follow the intricacies of TUMT's innovation journey (Van de Ven et al., 1999). TUMT's journey stretches over private business efforts and public healthcare, and represents a process where public and private actors in these two different contexts have engaged in the development as well as the commercialisation of TUMT, in their attempts to diffuse and embed the technology in the Swedish healthcare system. This thesis will not argue for or against TUMT as such, rather it aims to discuss med-tech innovation in the Swedish context of public healthcare and more thoroughly investigate the continuous yet difficult interactions between public organisations and private business in the med-tech innovation process.

With hindsight, we know that the TUMT technology did not to become a widespread technology in the treatment of BPH, yet it was utilised among a limited group of surgeons with positive results. However, the grand breakthrough once anticipated never occurred. What happened to TUMT and why did something seemingly so promising encounter such difficulties in becoming a widespread technology in the Swedish healthcare system?

1.1 RESEARCH PURPOSE

The aim of this thesis is to investigate a med-tech innovation process. This investigation implies a scrutiny of the possibilities and limitations of med-tech innovation in making contributions to the provision of public healthcare services as well as the ability to return a profit to the technology development firms. As stated above, the aim is not to evaluate the quality of the technology under scrutiny or to compare its usefulness to other existing methods. A central point of departure is that the method *was* and to some degree still is, valued by a critical mass of urologists as providing a viable outcome in the treatment of BPH. This implies that the TUMT device had a demonstrated *potential* to fulfil a function in the healthcare system and the treatment of BPH, to the same extent as any other previously existing methods. Consequently, the problematic innovation process is the focus of this study and the microwave technology case is used as a probe to capture important aspects of the challenges to med-tech innovation. The overarching purpose of this thesis is to understand;

"Which are the main drivers and hindrances to a med-tech innovation process that stretches over both a private and public context, and more precisely, which features, in what part of this context, supports respectively counteracts it?"

Before articulating the explicit research questions, I will discuss some fundamental starting points of the phenomenon of innovation in general and of medical innovation in particular, to position this study. Thereafter I will briefly discuss innovation from a policy perspective, including how policy makers handle new solutions in healthcare. Further, I will discuss how the usage environment is influenced by the policy agenda and the assumptions behind it.

1.2 AN INTERACTIVE PERSPECTIVE ON INNOVATION PROCESSES

Innovation is an extensively investigated phenomenon within several fields, and researchers hold quite diverse views on its characteristics, ranging from claiming that it is a phenomenon that can be managed and strategized to seeing it as a random occurrence, in particular in its early phases (Van de Ven et. al, 1999; Tidd et. al, 2001). This study is based on an interactive view on innovation processes, taking its starting point in an IMP (*Industrial Marketing and Purchasing)* approach, a research tradition which has been investigating innovation in industrial networks, emphasising the interactive character of the business landscape. Innovations are, within this research tradition, assumed to emerge as public and private organisations, combining their heterogeneous resources across organisational borders (Håkansson & Waluszewski, 2007).

Another field which has influenced this study is the STS (*Science and Technology Studies)* field. Studies within STS have investigated such topics as the social construction of technology and contributed with extensive works on knowledge production, emphasising the co-production of science and social order, hence the interconnections between science and industry (Bijker, Hughes & Pinch, 1987; Jasanoff, 2004; Latour, 1987; Callon, Law & Rip, 1986; Jasanoff, Merkle, Peterson & Pinch; 2001). Another crucial contribution to innovation studies is from the field of history of technology, with authors such as Kline & Rosenberg (1986) who pinpointed the intermingling of technology, scientific development and economy in the innovation process, showing how successful dissemination of innovation depends on complex interactions between commercial and technological spheres, thus pointing to their reciprocity in the innovation process (see also; Rosenberg 1970).

As a general point of departure, interactive and process-oriented studies provide pictures of innovations as a quite unruly - yet not random - and iterative process where new solutions move back and forth between the empirical settings of *development, production and use* (Mowery & Rosenberg, 1982; Van de Ven et. al, 1999; Håkansson & Waluszewski, 2007). Therefore, innovation is not merely an act of making a discovery or of novelty in itself, but rather a question of relating the new to different settings that are able to develop, produce and eventually create use among several users (Van de Ven, et al., 1999; Bijker et al., 1987; Håkansson & Waluszewski, 2007). This means that innovation cannot be ascribed to the efforts of a single person or a single source.

For example, Alexander Fleming is known as the discoverer of penicillin. However, even though he made a crucial discovery, the emergence of the new drug was not only his merit. In order to turn his discovery into something useful, an antibiotic drug, it first had to be modified and combined with a range of other social and material resources, a process which took over 10 years (Rosenberg, 1998).

Furthermore, innovation entails a large portion of uncertainty, firstly because the new brings forth changes that demand adaptation between the new and previously established resources and secondly because resources are assumed to be heterogeneous (the concept of heterogeneity will be further discussed here below in Chapter 2) (Van de Ven, et al., 1999; Håkansson & Waluszewski, 2007). To introduce a new solution, bringing it into use is thus a complex task due to the need for encompassing adaptations. Therefore, even if a new technology seems promising in a development setting and a company is willing to produce it, there is no guarantee that the new will become a widely-used solution. In fact, the majority of innovation journeys fail in the transition from prototype to widespread use, i.e., during the commercialisation phase (Rosenberg, 1996; Pavitt, 1991; Cooper, 1979). The high failure rate is contingent on the fact that the new solution has to find a critical number of users willing to pay for the new solution so as to cover the costs of production.

The user, in turn, has to consider how to relate the new solution to previously established social and material resources, thus assessing the benefits of embedding a new solution in comparison to the 'status quo' (Håkansson & Waluszewski, 2007). Innovation processes can then be portrayed as a dynamic interplay between two or more actors, which embeds the new into use requiring interaction between users and producers (Harrison & Waluszewski, 2007; Håkansson et. al 2009; Powell & Grodal, 2006). Close producer-user interaction can potentially reduce some of the high uncertainties of innovation processes since development is given an opportunity to align with previously made investments. To involve prospective users as early as a development stage was first suggested by Von Hippel, who coined the term 'lead users' (Von Hippel, 1986), arguing that users are capable of contributing to the innovation process (Von Hippel, 1988).

It is extremely arduous to forecast which solutions will become widely used and which will become failures given the presumed contextual contingency of innovation. However, innovation processes also have to be understood from the perspective of the larger structures into which they are embedded, that of science, technology, social and economy and how their complex connections

and reciprocal contribution to innovation influence the innovation process in a more general sense (Rosenberg 2010; Bijker, 1994; Callon et al., 1986). The interrelation between science and technological development of new medical solutions is of special interest, as the next section will move into innovation in healthcare, a context where the scientific aspect is present, both in the development and the use of new solutions.

1.3 MEDICAL TECHNOLOGY INNOVATION

With its starting point in a process perspective, this study will apply the three empirical settings of *developing, producing and using*[1] (Håkansson & Waluszewski, 2007) to investigate the innovation process of the focal microwave technology. However, several studies before this one have applied a process perspective to the investigation of medical technology innovation (for example see: Scott, 1990; Barley, 1986; Gelijns & Rosenberg, 1995; Gelijns et al., 1998; Shortell et al., 1987; Van de Ven, 1991; Nicolini, 2010; Grol & Grimshaw, 2003; Greer, 1986). Therefore, this section will discuss how this thesis relates to previous work on med-tech innovation and discuss its area of contribution.

The *development* of new med-tech solutions is identified as a close-to-practice phenomenon, where some of the most influential empirical studies uphold that the *practice-based characteristic* is a key feature of medical technology innovation (Von Hippel, 1986; Rosenberg, Geljins & Moskowitz 1998; Beimans, 1991; Rosenberg, 2009). Geljins and Rosenberg (1998) concluded that incentives to innovate, hence to develop new solutions, usually begin in medical practice, because practice is where the call for new methods arises (Gelijns et al., 1998). A statement which underscores the fact that new medical solutions *are not necessarily derived from a purely scientific research environment* (Rosenberg, 2009; Weigel, 2011 pp.45; Von Hippel, Thomke & Sonnack, 1999; Gelijns & Thier, 2002; Lettl, Herstatt & Gemuenden, 2006, Timmermans & Berg, 2003).
When practice is a source for med-tech innovation, physicians and other health professionals play a central role as sources of innovation (Von Hippel, 1986). This assumption is closely related to the lead-user concept where practitioners participate and even spearhead the development (Von Hippel, 1986). A study

[1] The settings of developing, producing and using (Hpåkansson & Waluszewski, 2007) will be further discussed in Chapter 2.

by Von Hippel (1976), which comprised 111 innovations (including many medical technology devices) found a user dominated development in the innovation process, emphasising that the users can be highly involved in both the development and production of new devices. This study builds further on such ideas of a practice-based, yet scientific development of new medical technology devices. The innovation process of microwave technology will be investigated as an inter-organisational process, hence something taking place in the interface between Swedish public healthcare, the users, and private business, the producers.

Furthermore, the *use* of new med-tech solutions has been studied by many scholars covering aspects as professional, organisational and systemic barriers to achieve widespread use (Fitzgerald et al., 2002; Ferlie et al., 2005; Berwick, 2003; Baldwin et al., 2006). For example, at the individual or clinical level, studies cover such issues as how new technology impacts social structures (Nelson & Yates, 1978). Coleman et al. (1966) made a 'classic' study on the social processes within a larger professional network and examined how these affected the diffusion of a medical innovation. Barley (1986) investigates the implementation of CT scanners in two different community hospitals, showing the ways in which new technology impacts social structures and order in the hospital (Barley, 1986). Ferlie et al. (2005) have studied how professional boundaries, demarcating medical specialisations, can hamper the spread of innovations in healthcare (Ferlie et al., 2005).

The studies on *organisational* barriers in healthcare point out that the accounting systems, characterised by short-term cost analysis and silo budgeting, will negatively impact the possibilities to embed new med-tech solutions into practice. The financial monitoring of healthcare is thus found to influence the adoption of medical technology innovations in practice (Adang & Wensing, 2008; Berben et al., 2011; Gelijns et al., 2013; Aldrich, 1987). Some of the latest studies acknowledge the notion of multileveled use, reflecting that medical practice – representing the direct users of medical technology – are embedded into a larger system of public healthcare which is politically governed. Paul Plsek (2003) argues:

"Systems are embedded within other systems and co-evolve. The boundaries of a complex system are somewhat arbitrary. We can say that a medical group is a complex system, which is embedded within a regional healthcare system, which is embedded within a national healthcare system, which is embedded

within a political system, and so on. The evolution of each of these complex systems influences, and is influenced by that of the other systems"

(Plsek, 2003, p.2)

The citation points to the many different dimensions of contextual specificity that has to be taken into consideration when a new medical solution strives to become embedded into use. The different levels of adoption have, among many others, been investigated by Grol and Wensing (2004), who propose six levels of analysis[2] (Grol & Wensing, 2004, p. 58). However, the multi-level complexities of embedding new medical solutions into use is commonly assumed to take place at three different levels, an individual, organisational and systemic level (Scott, 1990), even if other kinds of categorisations also exist. For example, Kimberly and Evanisko (1981) point to individual, organisational and contextual variables as the most central predictors of a hospital's adoption of technological innovations, and highlight the importance of context in understanding the diffusion of innovation in healthcare (Kimberly & Evanisko, 1981, pp.695- 697). Greer (1985) instead identifies three levels of decision systems at an individual, organisational and systemic level, which a new med-tech solution has to be related to during the 'adoption' process (Greer, 1985). This study will investigate the embedding of the microwave technology into a developing, producing and using setting through focusing on two *interactive levels* within and among these settings. The *specific level*, represents the clinic and healthcare practice and the *systemic level*, represents the management of public healthcare in Sweden in terms of management control tools, financial control and the organisation of public healthcare.

Furthermore, other recent works on medical innovations have studied the coherency between regulations of practice and the work of health professionals and found that the two are seldom compatible (Fitzgerald et al., 2005; Greer, 1994; Casper & Berg, 1995; Timmermans & Berg, 2010). Thus, pointing to how tensions between a practice-based logic and the systemic/organisational management hamper the possibilities for changes in the previously established healthcare organisations and therefore these tensions also obstruct the possibilities for new solutions to diffuse in healthcare (Fitzgerald et al., 2005). This disconnect between regulation and actual practice is contingent on the fact that

[2] The levels are: 1) the innovation itself, 2) the individual/professional, 3) the patient, 4) the social context, 5) the organisational context and 6) the economic and political context (Grol &Wensing, 2004, p. 58).

much clinical work depends on individual patient cases. Moreover, the boundaries created by standardised regulations are claimed to clash with unpredictable situations in medical practice (Berg, 1997; Timmermans & Berg, 2010). Several studies therefore point to an ongoing tension between needs for flexibility in practice, at an individual level, and a politically propelled standardisation of protocols in the management of practice, such as knowledge management and financial control tools (Nicolini, Powell, Conville, Martinez-Solano, 2007; Berg, 1997; Timmermans et al., 2010).

Conclusively, researchers have conducted extensive studies on such issues as the role of practitioners, hospital managers and organisational structures, covering broad issues ranging from the impact of economic organisation to medical practices (Fleuren, Wiefferink & Paulussen, 2004). Additionally, the mode of intervention has been investigated in the management literature, proposing different models of how to make new solutions diffuse efficiently into practice (Berwick, 2003; Plsek & Wilson, 2001; Denis, Hébert, Langley, Lozeau, & Trottier, 2002). Indeed, use has been identified as the most cumbersome part of the med-tech innovation process.

Nevertheless, even if studies of innovation in healthcare are so numerous and over the past decade have increasingly emphasised the usage context, focussing on many different aspects of the using setting, the vast majority stresses the development or usage context *alone* and addresses use in terms of '*adoption*' of new solutions in the healthcare system. Very few studies investigate med-tech innovation as a process which has to be related to the settings of *development, production and use*. In fact, Fitzgerald et al. (2005) conclude in their review on innovation in healthcare studies that:

"*Reviewing the literature underlines the shift away from linear models and identifies that the impact of variable contexts is under-researched. The separation of the discussions on creating new knowledge, diffusion of knowledge and innovations and knowledge management means that interconnections between the key influences remain unclear"*

(Fitzgerald et al., 2005 pp. 1433-34).

This study therefore contributes to previous studies by applying an inter-organisational perspective, based on an interactive approach, it investigates med-tech innovation as a context-dependent phenomenon, stressing the notion of *embedding* rather than adoption (Håkansson & Snehota, 1995; Ford et al.,

2003). Furthermore, this study emanates from the presumption that med-tech innovation follows the same 'disorderly' process as innovation in general, thus following the pathway outlined by several empirical studies (Håkansson & Waluszewski, 2007; Pinch & Bijker, 1987; Knorr Cetina, 1995; Rosenberg, 1982). It means that the aim is to move away from a narrow focus where development, production and use are viewed as separate and use of new medical solutions is reduced to simply 'adoption' (Akrich, Callon, Latour & Monaghan, 2002a; Rosenberg, 1996). This thesis will investigate med-tech innovation as an interconnected process, embracing the developing, producing and using settings as three settings into which a new solution has to become embedded in order to achieve innovation. It does not only strive to unfold the *key drivers and hindrances* in the developing, producing and using settings respectively (Håkansson & Wluszewski, 2007), but also to understand how the key drivers and hindrances are related and impinge on the innovation process.

Since the med-tech innovation process takes place, to a large extent, in the interface between public and private actors, the development of new solutions and usage of medical technologies is closely related to policy decisions. Therefore, it is relevant to reflect upon how med-tech innovations are considered in the policy discourse.

1.4 MEDICAL TECHNOLOGY INNOVATION IN POLICY

The search for medical technologies with the potential to enhance efficiency in the provision of healthcare services has grown over the past two-and-a-half decades. Both the healthcare policy and the innovation policy depict medical technology as a vital cornerstone for healthcare improvements as well as a source of economic growth. The Swedish governmental bill on research and innovation dated Fall 2012, states that:

"The opportunity to conduct larger joint clinical research projects could bring forth many positive effects, not only for patients that could receive more efficient and safer treatments, but also for the development of healthcare services in general, research quality, the development of business life and the growth of the Swedish economy" (prop. 2012 13:30 p .95, author's translation).

and

"Results from clinical research can contribute to an improved healthcare and aim to optimise existing treatment routines while at the same time contributing to the development and evaluation of new treatment methods based on new knowledge"

(prop. 2012 13:30 pp. 95, author's translation).

Consequently, new med-tech solutions are not only supposed to contribute to enhanced efficiency in the using setting of healthcare services, but research stemming from those same healthcare institutions is also supposed to generate new med-tech products and new companies. The pressing issue is then how scientific medical results are turned into solutions enhancing the 'efficiency of healthcare' while at the same time creating thriving businesses.

The picture provided by policy builds on a rather simplistic idea of the creation of new knowledge and how it is utilised in a business sphere. New knowledge is supposed to be derived basically from scientific arenas, often so called 'centres of excellence' (Clarysse, Wright, Lockett, Van de Velde & Vohora, 2005). Then new knowledge is transferred to a business setting where new companies produce the new solution (Baraldi, Ingemansson & Launberg, 2014). The major concern of Swedish research policy is thus how to create companies out of scientific research (prop.2012/13:30). The iterative patterns connecting the development and production of new technologies has gained more attention in recent policy (Vinnova, 2015). Nevertheless, a rather simplistic view on innovation is still overrepresented in policy documents, resting on basic economic assumptions of linearity of innovation processes (Konkurrensverket, 2014).

The idea of how new solutions shall be brought into use, that is commercialised in a manner conducive to companies earning profits and creating economic growth, is of particular interest to this study, especially because healthcare is predominantly a public sector in Sweden as well as in several other countries. Policy is therefore highly involved in creating the conditions for the presumed 'user market', which makes it relevant to discuss how policy stages the user conditions of its own healthcare market.

Commercialisation, from a policy perspective, is facilitated by improving the coordination between companies and "the market", that is users in the public healthcare sector. Swedish policy views standardisation *as the key to fruitful coordination*, already at a research level. However, according to the Swedish proposition on innovation policy, issued in 2012, it is stated that

small-to-medium-sized companies lack significant understanding with regards to the value of: *"*[..] *standardisation as an important component to the utilisation, commercialisation and proliferation of innovations*[..]*"* (prop. 2013/13:30).

Policy strives to make healthcare users as homogeneous as possible through control instruments (Berg, 1997). The tools of most impact in this mission are knowledge management tools, the most encompassing ones, in the Swedish system, being national guidelines. Guidelines are premised on the idea that there is one optimal solution for each medical intervention, a single option based on scientific evidence. Policy then puts pressure on healthcare, down to the specific level, to adopt the same, scientifically grounded solution (Fitzgerald et al., 2002; Berg, 1997; Ferlie, Fitzgerald, Wood & Hawkins, 2005). This policy approach pushes a few central issues: first, scientific facts are perceived as objectively true and universal and will create the same outcome independently of where in the healthcare system or by whom they are used. Secondly, this policy also pushes an idea of a certain hierarchy regarding which kind of knowledge is valued within the healthcare system. As put by Berg (1997):

"The protocol [guidelines], then, reinforces a hierarchy between different types of information and interventions: that which can be made explicit is more important, more scientific, more of value, than that which cannot be (or is not) made explicit"

Berg, 1997, pp.1085

In recent years, there has been a clear tendency towards more detailed regulations of the introduction of new technologies into Swedish public healthcare, paralleled by a political quest for more health economic evaluations (Vårdanalys, 2015:2). In 2014, SKL[3] wrote a report on how to create planned introduction of pharmaceuticals and med-tech solutions. In these planned introductions of new medical technologies, health economic evaluations are the foundation to assess the value of new medical technologies. The conclusion from central authorities is that the counties[4] lack sufficient *knowledge* to make rational decisions with regard to what kinds of devices are to be utilised in their specific organisations (TLV, 2014, SKL, 2014). Knowledge in this context refers to health economic assessments.

[3] SKL – Swedish Association of Local Authorities and Regions
[4] The Swedish healthcare system is decentralised. The 20 counties and 4 regions are self-governed.

By assuming that new solutions will be used according to national guidelines or other equivalent central control tools, by all possible healthcare providing organisations, the value which new medical technology methods can create for the users is decontextualized within this policy model. Indeed, this model continuously introduces new measures towards higher homogenisation in the provision of healthcare services. Therefore, this policy approach implies that to become successful, med-tech solution simply have to be valued in an ideal healthcare provision context and generate 'good numbers' within the frames of health economic models, which are taken to represent an allegedly homogeneous use setting. This study will instead stress the great heterogeneity in the local contexts of use of med-tech: the empirical case of microwave technology and the discussion in this thesis will therefore contrast the policy-driven decontextualized view of innovations.

1.5 RESEARCH QUESTIONS

Now that the case study and the different perspectives on innovation processes have been introduced, I shall specify my research questions. As already stated, the overarching purpose of this thesis is to understand:

"Which are the main drivers and hindrances to a med-tech innovation process that stretches over both a private and public context, and more precisely, which features, in what part of this context, supports respectively counteracts it?"

To address the purpose, the microwave technology will be used as an analytical probe throughout the innovation process and its three settings, developing, producing and using (Håkansson & Waluszewski, 2007). In particular, this probe will be used in order to identify the specific drivers and hindrances in a private and public context respectively, and also to understand how adaptations between these two contexts are enabled or obstructed. The specific questions are:

i) *Which are the main drivers and hindrances to embedding the microwave device into a) developing b) producing and c) using settings that emerge from private-public interactions?*

ii) How are the key drivers and hindrances in the developing, producing and using settings interconnected?

1.5.1 DELIMITATIONS

Medical technology embraces a broad area of devices, ranging from adhesive patches to robots. Whereas patches might have a somewhat more standardised user interface, most high-tech devices are complex technologies, entailing complex interfaces with the users (Barley, 1986). This thesis focuses on complex medical technology innovations. Healthcare users also range from small private clinics and open day-care centres to large, research-driven hospitals. This study only focuses on hospital users.

1.6 SUMMARY AND OUTLINE OF THE THESIS

This thesis is based on a case study within the domain of medical technology innovations, aiming to understand the main drivers and hindrances of such innovation processes, from early development to widespread use. If we want to understand how and if medical technology innovation creates positive effects in the provision of healthcare services, it is not enough to investigate a medical technology company, or a single hospital, or a development setting taken separately. It is rather a matter of firstly creating a picture of what an innovation process is, stressing its multi-relational and iterative nature. Secondly, med-tech innovation processes take place in the interface between public healthcare and private business. In order to grasp the disparate structures of these two contexts and the interactions between them, particular research tools need to be applied.

Therefore, the next chapter presents research tools forming the theoretical framework that has guided this study. The theoretical fundaments are derived from the IMP tradition and based on industrial network theory (Ford et al., 2003; Håkansson & Waluszewski, 2002; Håkansson et al., 2009). The aim with the theoretical discussion of Chapter 2 is to create a framework for the thesis through a discussion of how to understand and analyse the heterogeneous business landscape, the healthcare sector and the innovation activities taking place between these two contexts. The chapter also elaborates further on the specific research tools used in collecting the data and analysing resources' interconnectedness throughout the innovation journey of TUMT. The research

tool used is based on a 'resource interaction' approach - more specifically the 4R model (Baraldi, Gressetvold & Harrison 2012; Håkansson & Waluszewski, 2002). Chapter 3 is dedicated to methodological considerations such as theoretical starting points and choices made in delimiting the case, why this specific case was chosen and how the study was conducted. In Chapters 4, 5 and 6, the case will be showcased in detail. Starting with the very first developments in microwave technology, these chapters will explore the emergence of the company ProstaLund and the technological development of TUMT that took place in cooperation with several different public hospitals. The empirical chapters will also present the public management reform and the regulatory restrictions imposed in both developing and using new medical technologies. In particular, Chapter 6 shows the heterogeneity in the using setting by featuring four embedded cases of four different Swedish hospitals, each one using TUMT in a different way. Chapter 7 and 8 analyses the case and identifies and discusses drivers and hindrances in the innovation process of the focal microwave technology from an interactive perspective. Chapter 9 concludes the thesis by answering the research questions and Chapter 10 discusses policy implications as well as suggestions for further research resulting from the findings of this study.

2. THE THEORETICAL FRAMEWORK

This chapter presents the theoretical framework. Firstly, it discusses some basic assumptions of the business landscape, innovation in general and medical innovation in healthcare in particular. Secondly it discusses the theoretical tool applied to analyse the empirical material. The outline of the chapter is as follows: Section 2.1 gives a brief introduction to the IMP perspective and an interactive viewpoint in general; Section 2.2 elaborates further on innovation as i) an interactive and ii) an embedded and interdependent phenomenon; Section 2.3 discusses; i) the development and ii) use of new solutions in healthcare; Section 2.4 presents a set of research tools capturing interactive innovation processes.

2.1 AN INTERACTIVE POINT OF DEPARTURE

There are many disparate theoretical views of the landscape where business activities are undertaken and also several ways to interpret innovation processes (Waluszewski, 2004). The theoretical framework applied in this thesis is based on an IMP approach, *Industrial Marketing and Purchasing*. IMP holds an interactive perspective on business activity that proposes that interaction is the foundation of economic activity. It elucidates the ways in which companies strive to combine their resources with counterparts' resources over time and space in order to create value out of their resources (Håkansson & Snehota, 1995; Håkansson & Ford, 2002; Ford et al., 2003; Håkansson & Walusewski, 2002; 2007)

The interactive IMP perspective represents an empirically derived view based on an extensive series of especially qualitative empirical studies undertaken by IMP researchers since the 1970s (Ibid). These studies show that companies create lasting relationships and adapt their resources to each other so that the business landscape takes the shape of network structures (Håkansson & Snehota, 1995). Nevertheless, these observed patterns go counter to the most fundamental assumptions in economic theory where concepts such as the price

mechanism and competition - rather than interaction - are the dominant conceptions to explain economic activity (Håkansson et al., 2004; Snehota, 1990; Johansson & Mattsson, 1987). Despite the fact that interdependence is not a new phenomenon as such –it has always been present in the business landscape – it is of growing importance to explain economic activities. In a globalised economy, propelled by an increased pace of technological development, where firms have gone from highly vertically integrated activities towards a higher degree of outsourcing and specialisation, companies have become more interdependent than ever before (Gudeman, 2001; Håkansson & Waluszewski 2002; Håkansson et al., 2009). In a highly-specialised economy, interaction and adaptation to others, is thus a necessity in order to create value out of resources (Håkansson et al., 1982; Håkansson et al., 2004; Håkansson et al., 2009). Yet, interaction creates both positive and negative effects on organisations, since the different resource combinations they represent or the underlying intentions of different actors can never be fully known in advance (Ford et al., 2003).

The concept of interaction then captures value creation in the business landscape at large, implying that the value of the single company's resources depends on its relations to other companies and how the mobilisation of resources takes place in between companies over time (Håkansson & Waluszewski, 2002). The interactive IMP approach proposes that the internal issues of a firm should be analysed in a broader and inter-organisational context. Compared to a range of other approaches where organisations are commonly depicted as 'competitors', the interactive approach has a very different analytical starting point, in that it upholds the importance of relationships and focuses on the 'in-betweens' of firms in the business landscape (Håkansson & Ford, 2002). Considering that this thesis applies a process perspective on innovation, the interactive viewpoint of IMP enables the seizure of the aforementioned complex and iterative patterns of innovation processes that stretches over many different organisations in the public and private sphere.

2.2 UNDERSTANDING INNOVATION FROM AN INTERACTIVE PERSPECTIVE

The term innovation denotes something new that has been developed, produced *and* brought into widespread use (Tidd, Pavitt & Bessant, 2001). It is thus a phenomenon that is far more encompassing than the notion of discovery

or invention, as it includes the developing, producing and using of a new idea or solution (Van de Ven et al., 1999, p.9; Håkansson & Waluszewski, 2007).

Holding an interactive perspective on innovation implies that focus is shifted from the isolated intrinsic properties of a new solution to the issue of *adaptation*. The core issue revolves around the ways in which a new solution can be integrated and create value in the specific context bringing it into use. In turn, no invention, social or material, contains properties that are valuable for its own sake and innovation from this perspective is an utterly contextual and interactive phenomenon (Håkansson & Waluszewski, 2007).

Empirical studies on innovation put emphasis on the importance of interaction and that innovation is a combination of many different and heterogeneous[5] sources. An influential study that in detail mapped the iterative patterns of innovation is the longitudinal study MIRP, *Minnesota Innovation Research Programme*, a study synthesised in Van de Ven, Polley, Garud & Venkataraan (1999). With a large amount of qualitative empirical data from different cases the study shows that innovation is a consequence of the high diversity among actors in the business landscape. The business landscape in which innovations emerge is thus assumed to consist of heterogeneous organisations that form a "rugged landscape" (Van de Ven et al., 1999). The rugged landscape alludes to the heterogeneous set of resources that each organisation provides to the business landscape, creating an almost endless amount of possible combinations (Waluszewski, 1990). Therefore, when organisations of different forms and kinds interact and combine their heterogeneous resources – be they universities, companies or public hospitals – new resource combinations, innovations, take form as a consequence of mutual adaptations (Harrison & Waluszewski, 2008). As the innovation spreads among the heterogeneous organisations inhabiting the business landscape, the new solution tends to 'mutate' into related, but slightly different, forms from its origin. These changes in the new solution thus take form as the using organisations adapt the new to their own specific requisites or adapt themselves to the new solution, pushed by the necessity to create value from the new (Akrich, Callon, Latour & Monaghan, 2002b; Van de Ven et al., 1999). Therefore, the greater part of innovations is incremental in nature, involving smaller adjustments that build upon already established structures in the business landscape: these adaptation processes are recognised as the very fundament to innovation activities (Basalla,

[5] The concept of heterogeneity will be further discussed in section 2.4.2 here below.

1988; Håkansson & Waluszewski, 2007; Powell & Grodal, 2005; Basalla, 1988; Rosenberg, 1982; Van de Ven et al., 1999; Håkansson et al., 2009). Furthermore, innovation is found to occur within *established* producer-user relationships (Håkansson, 1990), which indicates the duration and depth of relationships in the business landscape. Research shows that a supplier-customer relationship on average lasts *over 10 years* (Håkansson, 1990). Another common pattern for innovations is to *return* to development *after* being brought into regular use, both a second and a third time, due to shortcomings that were not detected in advance (Van de Ven, et al., 1999; Håkansson & Waluszewski, 2007). The time frame is thus emphasised as an important factor for giving new solutions a possibility to emerge and become firmly embedded.

As a result, innovation cannot be treated as a linear phenomenon or as a homogenous process, from a long-term perspective innovation is something under continuous change (Hoholm & Olsen, 2012; see also, for example, Latour, 1996; Rogers and Shoemaker, 1971; Nelson and Winter, 1982; Ebadi & Utterback, 1984; Van de Ven, 1993).

Nonetheless, sometimes adaptations are difficult to accomplish, either because the new solution is fixed to very definite properties, or because it is too radical and hence challenges the prevailing structures from the ground, such as digitalisation (Pinch & Bijker, 1987; Håkansson & Waluszewski, 2007). Radical innovations are assumed to meet larger barriers to adoption and need more time to diffuse, since they represent big technological leaps that fundamentally change existing structures[6]. Radical innovations depend on longer time horizons and large investments before they may diffuse. This is because they are generally involved with larger systemic changes in technological, economic and social structures. However, radical innovation is a less common occurrence (Pavitt, 1995, p. 105).

This study also put large focus on the users since an interactive approach changes the perception of the user: rather than being an undifferentiated buyer, the user is perceived as a heterogeneous actor that interacts with producers

[6] An illustrative example of a radical medical innovation that required a very long time to diffuse is the development and use of the endoscope. It was conceptualised as early as the Middle Ages, but not brought into medical use until the mid-20th century. In order to further develop the first prototype into a useable device, it had to await advances in science and technology, concerning such factors as process production structures able to produce the device. The development of the endoscope into a valuable medical device was thus beyond the medical profession's control and instead depended upon advancements in related areas, in the producing and developing setting (Geljins & Rosenberg, 1995, p. 90).

and has a high involvement in the innovation process (Malerba, 2005, p. 391; Beimans, 1991). Kline and Rosenberg (1986) were among the first to include users through 'feedback links' in their investigation of technological innovations. However, the user-focused innovation studies were given attention with the seminal work of Von Hippel (1986). Coining the term 'lead-users', Von Hippel (1986) integrated users as a central part in the innovation process. Later, Riggs and von Hippel (1993) showed that innovations with high scientific importance tend to be developed by its users. They also concluded that innovations with a high commercial significance instead tend to be developed by manufacturers (Riggs & Von Hippel, 1993, p. 464).

Furthermore, empirical studies of innovation persistently point to commercialisation as the most cumbersome part of the innovation process. Numerous innovation journeys fail due to the high complexity of making the new solution compatible with aspects of the using setting, its history, norms, organisation, technology, values, etc. (Cooper, 1979; Steinmueller & Rosenberg 1994; Berwick, 2003). An interactive and user-centred perspective then proposes that new solutions, which appear to have all possible beneficial features in a developing or producing setting, might fall out as 'misfits' when brought into actual use. Nevertheless, involving users at an early stage can potentially diminish the discrepancies between the developing/producing setting and the users and thus facilitate adaptation (Von Hippel, 1994). The interaction taking place between firms, interconnecting their resources over time and space, is assumed to facilitate adaptation through mutual learning and sharing (Hallén, Johansson & Seyed Mohamed, 1991). However, long-term relationships and adaptations create interdependence in the business landscape, which will be further discussed in the next section.

2.2.1 EMBEDDEDNESS AND INTERDEPENDENCE IN BUSINESS AND HEALTHCARE

Adaptation makes companies interdependent since they have made social and material investments in creating specific solutions with their counterparts. Thus far it has been argued that adaptation – between heterogeneous firms – is a significant source of the incremental changes that lead to innovations in the business landscape. However, the creation of specific solutions between firms, which is a consequence of adaptation, simultaneously create path dependencies and condition what kinds of changes can be made within a specific relationship and sometimes even *obstruct* change. There are thus two sides to

adaptation and interdependencies in relation to innovation (Rosenberg, 1994). Interdependence create stability in business networks, due to investments in place, which will resist changes that are not in line with the current investments in material and social resources (Håkansson & Waluszewski, 2007). Established structures then set the frames for the trajectories of change that are open (Dosi, 1982). Therefore, opportunities to create incremental changes in a network are deeply embedded into the specific structures of the network, which in turn will shape the choice and path of particular ideas to evolve further (Bijker, 1987; Håkansson & Waluszewski, 2007; Van de Ven et al., 1999).

The concept of "embedding" is a way to capture the larger cross-boundary examination of resources' interconnectedness. If adaptation denotes the direct interconnections a resource is facing, the notion of embeddedness instead refers to the larger structure of couplings among resources in the network. When a resource is used in a specific resource constellation (Håkansson & Snehota, 1991, p.31) it will not only affect the directly interrelated resources, but resources that are interrelated in the second and third degree will also have to adapt, to a larger or smaller extent, to any changes undertaken on the focal resource (Håkansson & Waluszewski, 2002). Embedding is more pervasive than the concept adaptation in the sense that it can shed light on inertia in established structures, due to the many layers of interconnected resources.

I argue that the same line of reasoning about the business landscape, stressing its heterogeneity, adaptation and interdependence, can be held for a healthcare context. Healthcare has a strong path dependence, related to previous investments in, for instance, premises, devices and not at least knowledge structures in healthcare practice (Geljins et al., 1995, Nicolini, 2011). In the same way as the business landscape, the stable structures in healthcare simultaneously create opportunities as well as limitations for new solutions to evolve and diffuse[7]. Similar to industry, healthcare has, over the past century, expanded considerably and become oriented towards even higher specialisation – through

[7] An example is the diffusion of the endoscope into different medical specialisations which was strongly related to the previous treatment traditions and knowledge within each specialisation. Internal medicine was a fast adopting specialisation since laparoscopic methods made part of physicians' specialist training. Hence, the endoscope was in line with already established knowledge and technological structures. However, the different surgical specializations needed considerably longer time to adopt the technology. Surgeons' training at the time followed a traditional surgical pathway, which is very different from that of laparoscopy (Geljins & Rosenberg; 1995 pp. 259-62).

vertical disintegration of activities and an expanding number of sub-specialisations. Another consequence of the expansion in medicine as a field is the entrance of new scientific areas, such as chemistry, applied physics and biochemistry (Rosenberg, 2006 pp.95; Rosenberg, 2009). This expansion provides medicine with a large variety of resources and knowledge and thus a seemingly immense *opportunity and potential* to exploit resources across the borders of medical specialisations and scientific areas (Rosenberg, Geljins & Moskowitz, 1998). The next section shall continue to discuss some crucial starting points for developing new solutions in the interface between public healthcare and industry as well as framing some fundamental aspects of using new solutions in a public healthcare setting.

2.3 DEVELOPING AND USING NEW SOLUTIONS IN A PUBLIC HEALTHCARE CONTEXT

Public healthcare is not only a principal *user* of new med-tech solutions, but also a key actor in the *development* of the same. In order to understand the embedding of med-tech, we need to elaborate further on some basic traits underlying development and use of new med-tech solutions in healthcare according to previous empirical studies.

In the introduction to this thesis, it was argued that use and development of medical innovations are often studied separately. Either as development activities related to scientific work in a healthcare context or as adoption activities, referring to the multiple complexities of adopting new solutions in public healthcare (Fitzgerald et al., 2002; Scott, 1990; Grol & Wensing, 2004; Greer, 1986). The following two sections account for the basic processes underlying development and use of new solutions in a healthcare setting. Simply put, the following two sections will discuss why *both* development *and* use of new medical technology solutions should be perceived as a process that unfolds at the heart of medical practice, yet are closely intermingled with science (clinical research) and industry (firms pursuing profits).

2.3.1 DEVELOPING NEW SOLUTIONS IN THE INTERFACE BETWEEN HEALTHCARE AND INDUSTRY

Healthcare practice is indeed a crucial platform in the development of complex medical technologies, firstly because these new technologies, to a larger extent than, for example, pharmaceuticals, require direct testing by professionals in healthcare practice during development (Geljins, Russo, Hong, Brown, Ascheim & Moskowitz, 2013). Hence, few complex medical technologies are developed in laboratories outside of clinical practice (Geljins, Rosenberg & Moskowitz, 1998; Beimans, 1991; Lettl, Herstatt & Gemuenden, 2006). Med-tech innovation is thus identified as primarily practice-based and incremental in nature, in the very same ways as was argued above, regarding innovations undertaken in the business landscape (Geljins & Rosenberg, 1994; Riggs & Von Hippel, 1994; Biemans, 1991; Gelijns & Thier, 2002; Lettl, 2007). As put by Weigel (2011) "*Innovation in medical technology is very incremental in nature, as it is closely tied to the physicians' practical experience with existing devices*" (Weigel, 2011, p. 55). Therefore, as the new solution moves in between different medical areas, users will, in practice, continuously develop new features as to suit their specialisation's diverging needs and thus further develop the technology (Gelijns & Thier, 2002; Metcalfe et al., 2005).

Furthermore, empirical research shows that medical practice is closely interlinked with science, so that medical practice actively shapes the *scientific process of developing* new medical solutions (Rosenberg, Geljins & Moskowitz, 1998; Berg, 1997; Nicolini, 2010; Biemans, 1991). Firstly, physicians' work often includes methods based on scientifically derived solutions and knowledge: medical work involves the 'use of science'. Yet, at the heart of medical practice also lies practical contingency, implying that everyday medical practice contains a continuous stream of conflicting interests, ranging from unexpected treatment results to organisational issues, such as time pressure or budget restrictions, that coincide with care of patients. This high contingency in turn requires practitioners to handle unique situations (Berg, 1997) where clinicians inexorably will have to renegotiate methods in use, as they carry out their everyday work (Fitzgerald, 2002; Berg, 2007; Timmermans & Almeling, 2009). The unexpected outcome in everyday clinical work will in turn pose new questions for further investigation in research (Rosenberg, 2009; Rosenberg, 2010). Medical practice can therefore, at the same time, be

analysed as a *scientific unit* and as an *economically driven producing unit*.[8] Medical practice, which is embedded into an academic setting, thus has an interesting double role. Firstly, as a source of scientific knowledge in its role as developer of new methods and secondly as assessor of the scientific value and usefulness of a new device (Håkansson & Waluszewski, 2007, p.7).

Industry has, in a fashion similar to medical practice, been proven to contribute to science[9] (Rosenberg, 1970; 1985; Jasanoff, 2006). Empirical studies confirm that the relationship between industry and science is reciprocal and intermingled, meaning that science is an endogenous phenomenon, responding to technological development in industry, in the same loops as was argued for medical practice (Rosenberg, 1982; Murray, 2002; Rosenberg, 2006; Håkansson & Waluszewski, 2007; Grandin et al., 2004; Partha & David, 1994; Latour, 1987; Rosenberg, 2010). Rosenberg contends that:

"*Thus, the introduction of new technologies has often generated strong positive feedbacks in the appropriate scientific community. The problems encountered by sophisticated industrial technologies, and the anomalous observations and unexpected difficulties that they have encountered, have served as powerful stimuli to much fruitful scientific research in the academic community as well as in the industrial research laboratory. In this way, the responsiveness of scientific research to economic needs and technological opportunities has been powerfully reinforced"*

(Rosenberg, 2006 p. 88).

Science is from this empirically derived point of view not an isolated activity taking place outside the commercial sphere of the business landscape or outside medical practice. However, intermingled scientific and technological development, they are undertaken in two separate *social* contexts with different underlying incentives to engage in development activities. Technological de-

[8] For example, a clinic at a university hospital

[9] The fact that industry contributes to science can be contrasted to a policy perspective on the function of science in innovation processes. Innovation policy is concerned with transferring science into business, using models assuming linearity. Thus, policy is little concerned with the ways industry contributes to scientific development. The linear model has long been one of the most influential models in policy to mould technological development and innovation. It refers to a unidirectional process where each 'step' is detached from the others: scientific discovery ⇒industrial production ⇒ economic growth. Science is held to be the primary source of innovation, which leads to applied science, which in turn will generate economic growth (for example, see: Grandin, Wormbs & Widmalm, 2004; Pinch & Bijker, 1987; Kline, 1985)

velopment takes place for economic ends in an industrial setting, whereas science revolves around the scientific practice itself. Scientists are therefore, from this perspective, prone to engage in development of new solutions with regard to the achievement of a scientific accomplishment. Scientific development is thus fuelled by science as a professional practice (Partha & David, 1994; Riggs & Von Hippel, 1993).

The introduction to this thesis provided a brief overview of the different perspectives on innovation activities as represented in policy. With regard to the development of new solutions, innovation policy puts emphasis on science as the most important source of innovation, and furthermore how to *transfer* new scientifically derived solutions to the industry. However, based on the above discussion of science as a social practice which is influenced and shaped by industry, development of new med-tech solutions is rather a question of understanding the multiple processes underlying development and how they impact the innovation process. Drivers and hindrances to develop new solutions can derive from scientific endeavours and/or be prompted by economic issues. The central interest of this thesis is to capture the different drivers and how they connect the healthcare practice context, the medical science context and the industrial context in the development of new med-tech solutions.

2.3.2 USING NEW SOLUTIONS IN A HEALTHCARE SETTING

The use of new medical devices firstly entails the complexities of using new devices in medical practice, at a *specific level of use*, whereby the new solution has to adapt to social and material resources, for instance inside hospitals and at clinics. Secondly, use can also be studied from a *systemic level of use*, indicating a 'collective' yet indirect use. A new device can, for example be assessed by central agencies and in this way become a method which is embedded at a systemic level. However, embedding a new device at a systemic level cannot be equated with successful use at a practice (specific) level, even if such systemic embedding is assumed to promote the possibilities for new solutions to achieve widespread use within the specific healthcare system (Fitzgerald et al., 2002).

In the practice-based view of use (the specific level), the embedding of a new solution is undertaken by individuals in their specific using context. Several studies stress that individuals, by no means, are passive adopters of new solu-

tions: clinical work is a set of social and interactive acts that involve combining of specific knowledge and artefacts (medical methods and devices) by people in a specific using unit (Fitzgerald et al., 2002; Berg, 2007; Biemans, 1991; Garud & Rappa, 1994; Geljins et al., 2013). Another central part of clinical work revolves around the patient and the fact that clinicians have to combine their existing resources to best fit each patient's individual needs. Medical technologies comprise both technical/instrumental elements and social ones in the sense that they are operated with a specific treatment method which requires the clinicians to interpret the method and use it in relation to each individual patient's needs (Berg, 2007; Rosenberg et al., 1998). Therefore, the treatment outcome of complex medical devices has been shown to have a strong correlation with any single physician's capability to operate the machine and understand how to use it in relation to each specific patient (Weigel, 2011). The everyday work at the clinic is accordingly about adapting resources to best suit the patient's needs (Fitzgerald et al., 2002, Ferlie et al., 2000).

Nevertheless, the use of new solutions also has an economic implication in the provision of healthcare services. Public healthcare comprises non-profit organisations but it is still concerned with *economic use* of resources, because it is in the interest of public healthcare to use medical solutions 'efficiently'. The work of clinicians, carrying out healthcare services, is thus not only concerned with treating their patients with the best possible care, but also with how to achieve such care in the best possible way with given resources, that is by economising the use of resources (Ferlie et al., 2000; Fitzgerald et al., 2002; Grol, Bosch, Hulscher, Eccles & Wensing, 2007). Håkansson & Harrison (2006) state that "*An actor can influence the use of resources in two ways. First, by choosing which resources should be combined within its boundary and secondly with which other actors' resources the internal resources should be combined*" (Harrison & Håkansson, 2006, p. 232). Thus, the use of new medical devices is not a static adoption of a ready-made solution that has to be related only to the patients, but involves complex decisions about resource combinations from an economic, scientific and medical practice perspective.

The organisational and financial frames that underpin the provision of healthcare services set the structural constraints for how physicians can economise upon new solutions (Garud & Rappa, 1994). Geljins and Rosenberg (1994) contend that "*the way in which a new technology ultimately will affect costs depends on the manner in which it is incorporated into the larger system*

of medical care, how the profession chooses to use it and to modify it" (Geljins & Rosenberg, 1994, p.19). Thus, individual decisions have to be related to the larger system of healthcare and the actors' capability to combine their given resources at their clinics is constrained by the frames of the larger healthcare system at both a regional and national level (Nicolini, 2010, Plsek, 2003, Garud & Rappa, 1994, Grol et al., 2007).

Summing up, a new med-tech solution is simultaneously involved in two separate processes as it strives to become embedded into use in a healthcare context: one process is concerned with specific level adaptations in localised medical practice where researchers or practitioners make incremental changes. Meanwhile, the other process is concerned with a more general consensus at a systemic, often national, level, accordingly not considering adaptations at the specific level (Nicolini, 2011). Garud and Rappa (1994) explicate the phenomenon in relation to technological evolution: *"Thus, there are two processes that unfold simultaneously during the evolution of a technology. One is a process of inversion at the micro-level of individual cognition. The second is a process of institutionalization at the macro-level of shared cognition. It is at the nexus of these two processes that the form and function of artefacts are manifested over time"* (Garud & Rappa, 1994, p.359)

Embedding a new solution into use at a systemic level is therefore largely different from embedding it at a specific level. Healthcare authorities, at a systemic level, often assume an atomistic, hence abstract and context-independent, view of the scientific facts generated in clinical trials (Berg, 2007). When the results of clinical trials are used as the basis for control tools to manage healthcare, they are found to clash with experiences in practice (Ibid). A major reason being that clinical trials often fail to capture individual variance among patients. Patient groups such as pregnant women, children, elderly or patients with multiple conditions are commonly excluded as non-suitable (Berg, 1997; Geljins & Rosenberg, 1998). One such example is RCT (*Randomised Controlled Trials)*: Geljins & Rosenberg (1998) provide the example of coronary bypass surgery where only 4 to 13 percent of the patients could meet the standards of the RCTs. Nevertheless, the efficacy of coronary bypass surgery was established on this very small sample of patients, which allegedly is not representative of the entire patient population (Geljins & Rosenberg, 1998).

The use of med-tech innovation strongly depends on how any given practice

locally applies 'scientific facts' that are generated about the new (Nicolini, 2011). Scientific facts, in the shape of guidelines or other such centralised treatment recommendations, inevitably become a social and context dependent issue in relation to the physician and the patient (Fitzgerald et al., 2002). Yet, as was briefly discussed in the introduction, healthcare policy embraces scientific data as 'objectively true' and utilises it to create central control tools. In contrast to policy, this study departs from the idea that science itself is a social practice and adheres to the theoretical perspectives proposing that scientific knowledge in essence is not any different from other knowledge in the sense that it is objectively 'more true' or exogenous to the structures where it is used, rather it is a context-dependent phenomenon, without any objective truth claims (Knorr Cetina, 1995; Callon, 1995; Latour, 1982; Akrich, Latour, Callon & Monaghan, 2002a; Jasanoff, 2004; Latour, 1982, p. 29).

2.4 RESEARCH TOOLS CAPTURING INTERACTIVE INNOVATION PROCESSES

So far, the chapter has developed a theoretical view on med-tech innovation in both the business landscape and in healthcare. This section discusses the theoretical research tools applied to collect and make sense of the empirical data. Since this thesis focuses on the resource dimension, of embedding a med-tech innovation, the 4R model (Håkansson & Waluszewski, 2002) was applied to capture resource interaction. The 4R model was chosen because it provides an opportunity to investigate resource interfaces, established as well as emerging ones, in a larger web of interdependencies. Furthermore, the model is not sensitive to contextual differences per se, which was another crucial aspect to consider since the resources under scrutiny can be controlled by a public organisation or a private firm, or a construction in-between the two (Håkansson & Waluszewski, 2002; Baraldi et al., 2012). Moreover, resource interfaces have to be understood from the broader perspective of the innovation process as a whole and for this task the empirical settings of developing, producing and using have been applied (Håkansson & Waluszewski, 2007). The analytical tool 4R and the settings, developing, producing and using, stress that any new solution has to become embedded into each of these settings in order to become an innovation, that is, something brought into widespread use. The discussion of the research tools starts with the three settings of developing, producing and using and then continues with the 4R model.

2.4.1 DEVELOPING, PRODUCING AND USING – INVESTIGATING INNOVATION CONNECTING THREE EMPIRICAL SETTINGS

Each of the three settings embodies an *economic* logic for actors to engage in innovation activities (Håkansson & Waluszewski, 2002; Rosenberg, 1994; Håkansson & Waluszewski; 2007; Shih, 2009; Ingemansson, 2010; Linné, 2012;). Departing from an interactive perspective offers off hand that these settings are interrelated. The decisions to either develop, produce or use a new solution is based on different economic logics and represents different characteristics. Yet in order for innovation to take place, the three settings need to be able to benefit from one another. Although many different dimensions together shape the innovation process, the categorisation into three settings foremost focuses on the economic dimension, accordingly on the economic motivation for each setting to engage in innovation. These motivations can be described as the relative balance between risks and gains of engaging in innovation from the perspective of three generic empirical logics (Rosenberg, 1982), as defined by Kline & Rosenberg,

"Within the technological realm, it is possible to confine one's thinking exclusively to the certain kinds of performance criteria. If one were indifferent to cost considerations, for example, one could devise a large number of technically feasible alternatives for improving the speed of an airplane, or the durability of an automobile, or the purity of a chemical. But technical success is only a necessary and not a sufficient condition in establishing economic usefulness"

(Kline & Rosenberg, 1989, p.276).

A new solution has to create value in each of the three settings in order to become an innovation, even though the requirements of each setting will be different. The settings can moreover be closely interrelated: for instance, the very same organisation can deal with both development and use of the same solution. On the other hand, for a different solution, the settings can be very distant: for example, a radically new solution that has been developed in an academic/scientific environment might not yet have any predefined area of application, nor any production structure able to produce it. Such a new solution would have succeeded in creating value in the developing, academic, setting but not necessarily in any of the other settings. This thesis analyses then how the resource interconnections of each setting, hinder or drive the innovation process. This implies that the very same resource interfaces that drives in one setting might be a hindrance in another (Håkansson & Waluszewski, 2007).

DEVELOPING SETTING

The potential values from developing a new solution are generally uncertain since many disparate factors will impact future opportunities to gain value from the new solution. Nevertheless, the type of solution will influence the costs and opportunities to economise upon it, namely if it is radical or incremental. A radically new solution typically takes a longer time to develop, requires larger investments as it will need extensive adaptations in relation to established structures and is associated with higher uncertainty and risks. Thus, a strong impact on established structures means that many more resource interfaces must change in relation to the new, which is associated with higher costs (Ford, 1982; Håkansson et al., 2009; Håkansson & Waluszewski, 2002; Kline & Rosenberg 1989, p.276; Håkansson & Waluszewski, 2007). Incremental solutions, which follow the direction of already made investments in production and use will normally be easier to embed into all three settings (Håkansson & Waluszewski, 2007, p. 154; Baraldi, Gregori, & Perna, 2011). IMP studies show that it is cumbersome to relate development to production/usage structures, even if they are interrelated from the beginning. A new solution developed outside a specific business setting supposedly makes it even more difficult to relate to the producing and using settings.

Another pressing issue concerning the development of new technological solutions is that it requires mobilisation of resources. The high costs to develop new technological solutions stems from the requirement of additional assets as to develop a specific technology further. Firms can then choose to license their technology to other companies instead of developing it in-house. Therefore, "markets for ideas" or, as put by Arora & Gambardella (2001) "markets for technology" are potentially important to offer new solutions in need of support and additional resources, a possibility to evolve further. The idea builds on the fact that there are larger firms, with extensive resources and assets to further develop the new technology, thus creating a "market for ideas" for smaller firms (Arora & Gambardella, 2001).

PRODUCING SETTING

The most important issue for actors in the producing setting is to understand whether or not a new solution can generate beneficial effects for the potential users, since users are the source of revenues (Håkansson & Waluszewski, 2007, pp. 152-53). Production is motivated only if it generates revenue, because the economic logic in a producing setting is constrained to earning profits from producing the output. As put by Rosenberg (1982), *"In the civilian sector, the diffusion of an innovation is dictated by economic performance,*

that is, cost per unit of output". To achieve scale in production is therefore one fundamental precondition closely interlinked with an economic production logic (Perna, Baraldi & Waluszewski, 2015). However, to scale up production of a prototype in order to achieve a feasible cost per unit is not done in a twinkle due to path dependence in production networks stemming from 'heavy investments' in place (Rosenberg, 1982; Hughes, 1987). Any producing company therefore has to consider prior investments made in relation to its suppliers, sub-suppliers and customers. When one company makes changes in the existing production structure, such changes will relentlessly affect many others in the production network. Additionally, as a consequence, it commonly demands large investments to make extensive changes or create a new production process, due to the need for adaptation at several levels in the producing network.

New solutions that are not developed within the specific producer-user context, will find larger difficulties to become embedded since they do not naturally follow the direction of prior investments. Commonly, any change requires small steps, so as to give the network time to adapt successively. The new solution needs to be given the op*portunity to follow the same direction as previously made investments* (Håkansson & Waluzsewski, 2007).
While user needs are crucial to any producer, producers also have an important interface with the developing setting. Improvements or adaptations made in production, so to suit the new, are assumed to overlap with activities in the developing setting. These adaptations in the production process are perceived as an important component in the development of innovations (Rosenberg, 1982). As recognised by Rosenberg (1982) "*This [the production process] is a source of technological development that is not usually recognized as a component of the R&D process [..]* " (Rosenberg, 1982 p. 121). Any producing setting therefore strives to improve production processes (routines, skills and equipment) in order to reduce costs of labour per unit of output, yet in doing so they indirectly make contributions to the development of innovation (Ibid).

Instead, the more the new solution clashes with established production structures, the more challenging it will be to establish large-scale production. The decision that a producing company faces is to consider whether or not an investment in a new solution will render profits that may exceed the investments to be made. The producer's knowledge of what features of a technological solution are valued in a user context is thus crucial for assessing the sales and production volume necessary to obtain value from it (Håkansson & Waluszewski, 2007, p. 153).

USING SETTING

Users can economise upon a new solution in three different ways. The most clear-cut option is direct profiting from the investment in new technology. A second option is to decrease fixed and/or variable costs when using the new solution. The last option includes minimising the costs when introducing a new solution (Håkansson & Waluszewski, 2007). These are the economic possibilities to profit from when making changes in existing structures. Yet, creating a return on investment in any of the ways described above may include highly complex adaptation tasks. Since resources are shared between many internal and external organisational units, any change in an already established structure of resources will create a chain reaction on all directly and indirectly related resources. Once again, the *type* of solution is vital to the users' capability to economise upon the new when in actual use. As was argued above, radically new solutions will require larger efforts to become embedded, but can potentially generate even larger economic gains. The argument also holds true the other way around, the smaller the change, the smaller the opportunities to increase profits (Utterback, 1994; Håkansson & Waluszewski, 2007). Therefore, it is neither the 'inventing environment', nor the production company alone that is able to decide on the success of an innovation. The use context's ability to embed the new solution, and hence to create value in relation to the already established structures is a determining factor in the successful diffusion of an innovation (Van de Ven et al., 1999; Nicolini, 2011).

2.4.2 THE 4R MODEL – CAPTURING RESOURCE INTERACTIONS IN THE INNOVATION PROCESS

The following sections elaborates further on resources as an analytical concept and thus how resources and the 4R model will be utilised to study the medtech innovation process.

HETEROGENEITY

The perspective applied here assumes that resources are heterogeneous, a view which builds on the work of Edith Penrose (1959). Heterogeneity is a concept that indicates that resources are highly context-dependent (Håkansson & Snehota, 1995; Snehota, 1990). This means that a resource's value is determined by other resources to which it is coupled, likewise the interconnected resources also define a resource's area of use and its properties. The value of a resource is thus determined by other resources in the context that brings it

into use. Thereby resources have no intrinsic value (Håkansson & Waluszewski, 2002; Baraldi et al., 2012).

Furthermore, Waluszewski (1990) suggests that resources have an infinite number of features and that resources can be combined in an infinite number of ways. The specific features of a resource that are visible emerge in interaction with other resources, so that the currently active properties depend on its current interconnections. When these interconnections change, new, previously hidden, features are able to come forth (Håkansson and Waluszewski, 2002, p. 37; Håkansson et al., 2009 p. 68; Baraldi et al., 2012). Consequently, what we are able to capture are merely fragments of resources, namely those properties emphasised by the user, since only limited parts of the resource are utilised (Waluszewski, 1990). Therefore, it is not possible to appreciate the full capacity or potential of a resource or to decide what a resource is per se, only what it creates in relation to other resources to which it is interconnected.

For medical technologies, heterogeneity has the implication that no technological resources can be assumed to have an intrinsic value. Even the value of a simple device is dependent on the resources to which it is connected. For example, a very experienced physician will be able to identify heart murmurs quite easily using a stethoscope, whereas a training physician using the very same stethoscope will find it more difficult to identify the murmurs.

VALUE AND FUNCTION ARE CAPTURED THROUGH RESOURCE INTERACTION PATTERNS

If the value of a resource emerges through its current interconnections, it can be defined on the basis of its ability to add value to other resources (Harrison & Håkansson, 2006; Baraldi et al., 2012; Holmen, 2001). The understanding of resources interaction and adaptation unveils not only the subjective value created in each context, but brings forth that value is not static but will change over time as other, directly or indirectly, related resources changes. However, it is important to underline that value is not to be put on a par with measuring direct economic gains (Håkansson & Olsen, 2015). Value is a way to understand the process that leads to economic gains in the end, but it is not a specific objective measure such as price, since value is subjective to each specific resource combination. This variability means that as the interactions underpinning a resource *change*, the new interaction patterns will alter both the features and the value of any specific resource (Håkansson & Waluszewski, 2002).

In relation to innovation processes, it is pivotal to understand how established resources change in relation to the new and vice versa, and how such changes affect the outcome in the current resource structure. The outcome of *resource interaction* will therefore define resources and what they essentially are, thus deciding on their current value (Snehota, 1990). This implies that *the very same resource can create different outcomes in different constellations*. The interconnected resources, social or material, such as physicians' expertise or medical equipment, will thus determine the functions and outcomes of the focal resource in use.

EXPLOITING THE POTENTIAL OF RESOURCES

Within the 4R model resources are assumed to be *path dependent,* that is, their features emerge due to a history of earlier interactions. Even if the imprints of previous interactions are hidden in the present combination, they still matter since they can impinge on the interface to other resources. Old and hidden features in a resource's present interaction are able to create both hindrances and drivers to new interaction patterns. Thus, new influences from new interconnections to other resources, can create "frictions" that are able to provoke old features of resources to reappear (Håkansson & Waluszewski, 2002 pp. 222-224). Moreover, the intended area of use at the start of a development process is not necessarily coherent with the final area of use where a new solution will be embedded into (Van de Ven et al., 1999, Håkansson & Waluszewski, 2007). For example, behind the drug Viagra was a long and dedicated search for a drug to treat cardiovascular diseases, but eventually, in clinical trials it turned out to have better effects as a potency-enhancing pharmaceutical (Li, 2006). This uncertainty on which values and features of resources eventually will emerge is due to the assumed heterogeneity of resources, which implies that they carry features that are 'hidden' or unknown in existing resource combinations (Latour, 1987; Snehota, 1990).

The implication of resource heterogeneity for medical technology innovation can be contrasted with the aforementioned context-independent approach in randomised controlled trials (RCTs) and the opportunities to capture the "unexpected benefits of medical research", as articulated by Rosenberg, Geljins and Moskowitz (1998). A typical pattern for medical innovation is that it moves between different medical specialisations (Geljins & Rosenberg, 1995). When a new medical solution is brought into clinical practice, it normally finds new areas of use as new, previously hidden functions are discov-

ered. The potential to exploit the benefits of medical solutions can be comprehended and analysed through resource heterogeneity. From a resource perspective, it is ultimately the use context's ability to exploit the heterogeneity of a new medical solution and hence to discover new patterns of interaction, that decides upon its potential.

However, a user can exploit a specific resource only to a certain extent: the user can decide *which* resources to combine and *with which other* resources to interconnect to (Baraldi et al., 2012); resources can be considered as to be 'doubled-faced' in the sense that they are attributed to both a provider and a user at the same time. Therefore, a user can never have full control of a resource, as much as the provider of a resource can only shape some of its features and extract some of its value. The *using context* then determines the value of a resource through exploiting it in close relation to current activities and established resource structure (Snehota, 1990).

RESOURCE INTERFACE AS FOCAL POINTS FOR RESOURCE INTERACTION

The underlying interaction is what essentially gives features and values to a resource. Therefore, it is not the resource per se that is of interest to capture, rather what will happen between resources in the *interface* which connects them. The continuous shaping of a focal resource in a specific context and its outcome when used can then be understood through studying its interfaces with other resources and how they change over time. Capturing these interfaces is the key function of the 4R model, which helps conducting analysis with a starting point in a focal resource (Håkansson & Waluszewski, 2002; Gressetvold, 2004; Baraldi & Waluszewski, 2007). As this study aims to capture hindrances and drivers of innovation, relevant changes are not only in the direct interface, between the focal resource – the microwave technology – and directly related resources, but also to resources that are related in second and third degree to the focal resource.

This continuous stream of resource interactions entails a continuous process of adaptation where resources will be shaped and reshaped, rejected and reconnected. Employing resource interfaces as the focal points of analysis allows an understanding of the variable consequences the microwave technology creates in the different contexts where it is developed, produced and used (Håkansson & Waluszewski, 2002; Baraldi, 2003, p. 21).

2.4.3 THE 4R MODEL AND FOUR RESOURCE TYPES

Resources can be divided into four types, which belong in turn to two categories, **products and facilities,** which are physical resources whereas **organizational units and business relationships** are social in their character (Håkansson and Waluszewski, 2002; Baraldi, 2003; Baraldi et al., 2012). The social resources fulfil an important function in relation to the physical ones, in that they have a "*multifaceted role in mobilising, developing and cementing physical resources to related interfaces*". And further, "*The knowledge and experience of how to combine physical and organisational resources is an ability of the individuals representing them - but it is also a collective knowledge, influenced by a larger economic system*" (Håkansson & Waluszewski, 2007, p. 157). We now present each of the four types of resources:

Products include physical artefacts, even if they are not viewed as given or neutral objects being transacted from point A to point B. In the 4R model, products emerge from interaction (Baraldi, 2003; Håkansson & Waluszewski, 2002 p.22). The network perspective proposes that the features of a product are shaped and created in interaction (Håkansson & Waluszewski, 2002, p.35). Furthermore, products are any kinds of artefacts like raw materials, components or an end product ready to use. They are further assumed to be changeable, since they move around in many diverse settings and have to relate to a large number of other resources in unique combinations (Håkansson et al., 2009, p. 67).

Facilities are the second type of physical resources which are place-bound. Facilities tend to be stable, which make them an important interface to other, more swiftly changing resources. In interlinking facilities, companies create opportunities to save both money and time. Further, due to such interlinking, facilities can be under the influence of many business units at the same time, yet bound to a specific place. Examples of facilities are production plants, research facilities and warehouses (Håkansson & Waluszewski, 2002).

An organisational unit is a resource of social character referring to the knowledge, competence, organisational structure, routines and skills bound in an organisation through its personnel (Håkansson & Waluszewski, 2002; Baraldi, 2003). When an organisational unit interacts with a counterpart, its *ability* to interact is a crucial part of the organisational unit's skills. To succeed with interaction demands competence in many different areas, such as adapting existing knowledge and technological structures to other organisational units. The method – being a form of knowledge – to operate a medical technology

device is thus a social resource within the boundaries of the organisational unit (Håkansson & Waluszewski, 2002 p. 36, Håkansson, Ford et al. 2009 p. 68).

Finally**, organisational relationships** connect two organisations and are special types of social resources that are time-dependent. The importance of the time-dimension is due to the relationship's dependence on past as well as present interactions (Håkansson & Waluszewski, 2002a). A relationship is a result of interactions between business units over time, which contain both material and immaterial investments. Therefore, a mixed range of resources characterises the relationship, such as joint routines and exchanged knowledge, which impact the interacting companies' routines and knowledge and physical resources, such as facilities and exchanged products. Organisational relationships have varying degrees of thickness (Håkansson & Waluszewski, 2002; Håkansson & Waluszewski, 2007). Thickness refers to the character and number of resources shared in between two counterparts. In any business relationship, there is a continuous and reciprocal adaptation of the resources of the two companies. In this way, companies create 'quasi organisations', which blur their boundaries and make it so that resources cannot be fully controlled by one part alone (Håkansson & Snehota, 1989; Håkansson & Prenkert, 2004).

2.5 SUMMARY OF THE CHAPTER

This chapter has presented the theoretical framework stressing that both the business landscape and the healthcare setting are characterised by interdependence as organisations create relationships over organisational borders. The med-tech innovation process has been described as close to clinical practice, yet closely intertwined with an academic/scientific context and with industry. The process whereby a new solution is brought into use was described as taking place at two different levels simultaneously, at a systemic level and a specific level. Policy is furthermore assumed to affect the larger economic structures of public healthcare. Since innovation activities are undertaken in the interface between public healthcare, industry and policy it is therefore supposed to influence the boundaries of clinical practice where new solutions are developed and brought into use.

To analyse the specific innovation process of the TUMT microwave technology, the three empirical settings of developing, producing and using will be utilised as a way to grasp what hindered or drove these different set-

tings to engage in the development of the microwave technology. More precisely, a set of different resource interfaces will be guiding the search in each setting.

The picture outlined above, with regard to the interactive business landscape and the heterogeneous characteristics of healthcare practice, is quite different from the policy picture as was described in the introduction. Policy views the users, healthcare practice, as atomistic and passive receivers of new solutions, and healthcare policy to a large extent strives to make the users more homogeneous through centralised knowledge management control tools. Against this background, this study aims to understand why a med-tech solution so promising according to several indicators, had such difficulties to achieve widespread use in the Swedish healthcare system. The study accordingly sheds light on specific key factors influencing, both as drivers and as hindrances, this specific innovation process. The next chapter will discuss how this was conducted and its methodological considerations.

3. INVESTIGATING INTERACTION – ACCOUNTS OF THE RESEARCH PROCESS

One would imagine a study to start with a clear-cut question that one seeks to answer in a precise pathway of succeeding research steps. That would have been a very comfortable beginning, but I would describe my research process as iterative rather than linear and certainly messy rather than orderly or stepwise. This chapter will unravel and present the research process and choices made along the way, as well as the methods used to conduct this study.

The chapter starts with the background of the study and the different choices made with regard to the empirical material and why the study took certain directions along the way. The next section presents a few comments on conducting case studies in general and how we can learn from cases - and it also discusses methodological consequences of an interactive approach and the consequences of using the 4R model as the backbone to collecting and structuring my data. Lastly, the data gathering process and oral and written sources will be accounted for.

3.1 BACKGROUND AND CHOICES IN THE CONSTRUCTION OF THE EMPIRICAL CASE STUDY

My research journey started with a curiosity towards innovation processes in healthcare and a wish to understand whether innovation processes were any different in a healthcare context compared to an innovation process undertaken only in the business landscape, and, if so, how these differences are manifested. The most apparent difference that comes to mind is that, in Sweden, the med-tech innovation process stretches from a private to a public context. It was therefore not solely a question of capturing a technological innovation process, which demands both social and technological understanding of technology development, but it also demanded a deeper understanding of the adaptation between two fundamentally diverging settings in terms of private and public actors and organisations. Consequently, the major challenge

in conducting this study was to capture the specific innovation process in these two contexts.

During a master course in product development at Uppsala University, I wrote an essay on ProstaLund and its microwave technology where I used the 4R model as my investigation tool for the first time (Håkansson & Waluszewski, 2002; Baraldi et al., 2012; Baraldi 2003). Then, before enrolling in the doctoral programme, I worked as a research assistant at the STS-centre at Uppsala University. I was assigned to conduct follow-up studies on life science companies in an ongoing research project at the STS-centre[10] (Waluszewski, 2004).

The data about the life science companies in the STS study dated back five years in time when I initiated my follow-up studies on the companies in 2005. Few of the companies were still 'alive' and those who had survived were seldom self-sufficient. The findings in the Uppsala life-science study indicated that ProstaLund's situation represented a common picture of the development and commercialisation challenges of small-to-medium-sized med-tech companies in Sweden at the time. The TUMT technology stood out as an interesting case to further investigate in order to comprehend med-tech innovation processes since it, despite its support in many different contexts, was experiencing difficulties becoming commercialised and which could not be dismissed as a mere 'market failure'.

The fact that the technology had first been developed in Sweden in the early 1990s and was still used in the Swedish healthcare system in 2005 (despite which the company ProstaLund experienced difficulties to commercialising their product in large-scale) was perhaps the conclusive factor that settled my investigation object. Another factor that made this particular technology a relevant and viable object of investigation was the fact that it is used in the treatment of a common disease with high cost implication for healthcare production. Since a vast portion of the male population is affected by BPH and in need of treatment, it enhances the economic incentives for healthcare to search for an alternative therapeutic treatment to cure BPH. Therefore, I hypothesised that it would be more difficult for healthcare providers to reject

[10] Before my official acceptance to the doctoral programme, I made part of an ongoing study at the Uppsala STS-centre at Uppsala University. This study was initiated in the 1990s aiming at 'mapping' all life-science companies in the Uppsala region. My work was a follow-up study of all the medical technology companies five years after the project was first initiated. Interviewing about 15 companies in the med-tech field gave me a picture of the companies' problems and the kinds of questions they were struggling with daily.

an alternative treatment promising great savings than it would a treatment for a disease with marginal effect on healthcare provision. Furthermore, common diseases, like BPH, are normally visible in the hospital organisation, such as in budgets, regulations, treatment recommendations and policy documents. Studying a treatment for a common disease potentially increased my chances of finding data, which, in turn, enhanced my chances of pinpointing the economic effects and therapeutic and scientific outcome of the treatment. Microwaves, therefore, seemed an attractive example of a med-tech innovation process from more than one perspective.

I would like to stress that the technology has been used as an example that has allowed me to follow the process of med-tech innovation from when it was initiated in public healthcare, to when it was produced in a private production structure and back to its use in public institutions. This thesis is not concerned with proving or weighing any pros or cons of alternative methods in therapeutic BPH treatment, but with understanding of the complex mechanisms behind med-tech innovation.

CHOOSING FOUR DIFFERENT USER SETTINGS

This study contains four 'mini cases', describing four different hospitals and their involvement in the innovation process of microwave technology. Hence, the research design is an embedded case study (Easton, 1995, p.480). Initially the focus was on the innovation process and how this proceeded technologically and methodologically/medically at a specific level, thus investigating BPH treatment in two of those four, clinical practices. However, as the data gathering proceeded and 'moved upwards' in the healthcare organisation, scratching on interfaces at a systemic level, I realised that there was much more to the process of med-tech innovation than I had previously expected.

Half-way through the data gathering process, it was difficult to pinpoint what was missing. I failed to make sense of the real essence of my data with the first two hospitals I studied. I chose to continue to investigate two more hospitals that had been a part of TUMT's development/use. Firstly, I had to make sense of the different patterns outlined in the first two hospitals. Secondly, I wanted to understand the various roles of the hospitals in the innovation process as they had all been part of the process at some point in time. Another interesting aspect was that the hospitals ranged from large university hospitals to one medium-sized and one small regional hospital. In some way or another, they had all been involved in developing, testing and using the microwave technology, but at different points in time and in slightly different

ways. Their roles in relation to the innovation process were thus my main interest. Consequently, I arrived at a broader picture of the healthcare landscape in which the microwave technology had moved over the past two decades. It had survived, but had hardly made any larger profits for the producing company in the Swedish context of use. I therefore wondered if perhaps there was something to the fact that all four hospitals had contributed to the innovation's continuity in the system, or whether it was a question of different kinds of needs between the hospitals occurring at different points in time. Further, did they follow the same using patterns? I did not know the answer at the time. Nor was I fully sure of the importance of studying use at several hospitals, or if it would render a more complete picture of the complex interface between public–private and its consequences for the innovation process.

FINDING NEW INTERFACES AT A SYSTEMIC LEVEL IN THE HEALTHCARE ORGANISATION

When I first initiated the study, I did so at the urology departments in different hospitals as to investigate the specific level of interaction patterns. Nevertheless, starting out on one end, the study successively grew, as the search for interfaces brought me to more unfamiliar dimensions of the healthcare contexts. First and foremost, I would say that delving into the organisation of public healthcare was crucial, but it made the healthcare context grow exponentially as wholly new and unfamiliar interfaces unfolded. Interfaces that were less technical and more of a social/organisational character increased in importance and the systemic level appeared to be absolutely necessary in order to understand the specific level processes of embedding the technology into use. Admittedly, conducting network studies is always a matter of handling multiple layers of complexities (Håkansson & Waluszewski, 2002, p. 25). However, such an exercise is not undertaken randomly, which was why I needed something that could guide me in this search: therefore, the next section firstly discusses the methodological choice of conducting a case study and secondly explains how the 4R model guided this study and the methodological consequences of investigating innovation from an interactive perspective.

3.2 METHODOLOGICAL CONSEQUENCES OF INVESTIGATING INNOVATION THROUGH THE LENS OF INTERACTION AND THE 4R MODEL

The purpose of this study is to investigate the drivers and hindrances of the TUMT med-tech innovation process. However, as was outlined in the introduction of this thesis, innovation is a phenomenon that can be studied from many different perspectives. Furthermore, the choice of theoretical underpinning in the investigation of innovation, that is the underlying assumptions of the nature of economic activities and of resources exchanged in the business landscape, will influence what methods and methodology can be applied to conduct a specific study as to answer its purpose.

Therefore, the interrelation between the research tools, theoretical underpinning and methodology are central to the outcome of this study, hence different theoretical perspectives and tools will generate disparate pictures and answers about the very same phenomenon. Håkansson and Waluszewski (2002) suggests that the images of reality we can create are only fragmentary and carry imprints of the research tools applied. Snehota (1990) argues along a similar discourse and suggests that all theory and use of concepts inexorably will reduce the phenomenon studied, since certain aspects, through the 'filter of theory', are discarded as non-relevant to the phenomenon under investigation. Consequently, no research process is held to be neutral, rather it is an unattainable task to reconstruct a 'true picture' of reality, since it is impossible to disclose all components of a certain phenomenon. What then, can a case researcher do to delimit uncertainties?

The possibility at hand, is to reduce uncertainty as much as possible by providing profound insights and transparency, as to enhance the "trustworthiness" and the plausibility of the research process and its results (Merriam, 1988; Heider, 1988). One of the core aspects to be discussed is therefore concerned with how theory and purpose are related to the choice of conducting a case study.

3.2.1 WHY A QUALITATIVE CASE STUDY?

The theoretical assumptions underlying this study rests on the basic principles that the landscapes – business and public healthcare – where the innovation process evolves are *interactive* in nature and that the resources in these landscapes are *heterogeneous* (Snehota, 1990; Baraldi et al., 2012). The case study

approach was chosen firstly because an interactive perspective implies capturing a highly complex empirical phenomenon, i.e., activities undertaken in the business landscape. The common perception of the activities undertaken in the business landscape is that of 'business exchange'. However, an interactive perspective conceptualises 'business exchange' as having a content, which over time give rise to *relationships* between business units, thus implying an investigation of the underlying resource interactions. As put by Håkansson and Waluszewski (2016) "*To put it briefly, business exchange includes buying and selling, which in turn includes using, producing and developing activities that all take place in different contexts, in relation to a number of historical and contemporary social and material investments in place*" (Håkansson & Waluszewski, 2016, p. 446). Therefore, the theoretical starting point of this thesis implies an investigation of highly complex sets of historical and contemporary resource interconnections, which are both material and social. Furthermore, the overarching purpose of this thesis is to capture key drivers and hindrances of the innovation process, in the settings of developing, producing and using and the method had to be consistent to this purpose and the theoretical point of departure. Case studies tend to provide a rich material, which is a crucial precondition to enable a thorough investigation of the resource interaction taking place in between organisations and therefore a case study approach was the most suitable method given both the purpose and the theoretical framing. Furthermore, case studies have been found to be a suitable method to unfold interaction and relationships (Dubois & Araujo, 2004) and to be appropriate for studying longitudinal change processes and dynamics in single settings (Van de Ven & Poole, 1990; Eisenhardt, 1989).

Nevertheless, it can be difficult to create order in a rich material. The 'case approach' undertaken in this study has been an iterative process wherein the data collection and analysis have developed concurrently, reflecting the fact that case studies are long learning processes where questions tend to be rephrased over time as the study proceeds (Flyvbjerg, 2006; Dubois & Gadde, 2002; Ragin, 1994). Ragin and Becker (1992) suggests that the researcher will not know what the case is about until the very end stages of the research process. The pivotal question, 'what is this investigation a case of?' will emerge gradually during the process (Ragin & Becker, 1992; Dubois & Araujo, 2004). This research process has indeed been a long learning process which has wandered across new fields in following the focal technology, in turn forcing the process to take new turns in order to explain the newly revealed patterns. Likewise, it has by no means been linear, notwithstanding the conscious search for

resource interfaces. The sections to follow will describe how the data was collected and analysed and the role of the 4R model in these processes.

3.3 COLLECTING AND ANALYSING THE DATA

The 4R model (see chapter 2) has functioned as a methodological tool through which the research process has been shaped and the data have been analysed. The search for interfaces was undertaken through the lens of this tool and the microwave technology was used as a probe, the focal resource, in the search for interfaces. The 4R tool should be understood as the backbone of both the data collection process and the analysis of the data (Dubois & Gibbert, 2010, pp. 129-130).

Furthermore, the 4R model allowed a systematic gathering of data without considering the differences between a public and private context, since this model stresses that resources are not bound to any predefined borders, neither spatial nor organisational ones (Strömsten & Håkansson, 2007). Nevertheless, it grasps the differences between private and public, through studying resource *interaction* and changes in resource interfaces. On the one hand, this research tool offers a systematic data generation and the fact that it focuses on four specific typologies makes it possible to systematise the data. On the other hand, it is an 'open' search tool as it unconditionally searches for interfaces, yet not neutral in the sense that it takes 'anything' into consideration (Håkansson & Waluszewski, 2002).

The next section, 3.5.1, describes the data collecting process and 3.5.2 discusses how the data was analysed.

3.3.1 DATA COLLECTION

Interviews have been the main source of data, which is acknowledged by Easton (1995) as one of the most valuable sources to study interaction. The data collection started with interviews first in the company ProstaLund and then continued to identify the hospitals that were most central to the development and use of the microwave device. If the company was an easy access point, the healthcare context was more cumbersome. Some periods were more challenging than others; very often the physicians were otherwise occupied and it was difficult to gain access to them and conduct interviews. In most cases, hospital management was easier to access than nurses and physicians. When eventually accessing most of the respondents identified during this jour-

ney, it had involved time-consuming efforts. The interviews were continuously complemented with secondary sources as a way to enhance knowledge about such issues as regulations for medical technology, control tools, procurement procedures, legislation and not the least theoretical literature belonging to the New Public Management (NPM) doctrine.

Even though NPM is discussed broadly within many different disciplines in the social sciences, this study will treat NPM as an empirical phenomenon. This is also the reason why no reference is made to NPM in the theoretical chapter. The empirical relevance of NPM for the Swedish healthcare sector was not easy to grasp at first: if one went about asking questions related to a phenomenon known as New Public Management in 2006, not one of the respondents in this study would have even heard the term. Still NPM was clearly causing organisational changes in healthcare that became more and more visible during the process of gathering data. Therefore, it was necessary to learn about the theoretical stances behind the doctrine of NPM so as to make sense of the organisational changes that were described during the interviews. It was necessary to lift above the respondents' perspectives and understand the changes from a systemic perspective. Consequently, the process of collecting data was an intertwined procedure between primary and secondary sources. Thus, following the standpoint of Czarniawska (1998), who states that using secondary sources can be a fruitful way to deepen the picture created from interviews.

The data collection process can be divided into four different phases. They are schematically described in Table 1 here below, so as to give an overview of how the process proceeded. The different phases overlapped slightly. However, more importantly, the data collecting process advanced in two 'loops'. Phase 1 started in 2005, conducting interviews with the company ProstaLund. By the end of 2006, it continued with Phase 2 by interviewing physicians at Örebro University Hospital and Uppsala Akademiska Hospital. In 2007, the same hospitals were further investigated and by the end of 2007 the systemic level of public healthcare was the new focus, i.e., the NPM doctrine and the managerial level at the two hospitals, Örebro and Akademiska, and policy documents. Nevertheless, the process started over again in 2009, following the very same loop of data collection. In the second round, more interviews were conducted with the company ProstaLund such that in 2008 it had undergone fundamental organisational changes with new owners and a new CEO. Additionally, two new hospitals entered the study in 2009, namely Kalmar Regional Hospital and Lund University Hospital. Therefore, phase 2 and 3

also started over in these two new, hospital contexts. The larger set of data generated during the second round required even more input with regard to the user settings' organisational structures and the systemic level of public healthcare, i.e., Phase 4. The very last interviews were undertaken in 2010.

	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**
Empirical field	ProstaLund: The company, the technology and the disease	The developing setting: Urology departments engaged in the development of TUMT/PLFT	The user setting: Attempts to embed TUMT in four public hospitals Hospital organisations	The user setting and its organisational structure: The Swedish healthcare sector
Primary sources Interviews with respondents at:	ProstaLund	Developing Urology departments/clinics: Örebro Regional hospital Uppsala Akademiska Kalmar Regional hospital Lund University hospital	Using Urology departments/ clinics: Örebro Regional hospital Uppsala Akademiska Kalmar Regional hospital Lund University hospital	Hospital executives
Secondary sources	Regulations for med-tech, technology functions, BPH disease and implications	Education directions for urology specialisation, treatment directions for BPH, internal billing systems of BPH treatment, alternative methods and outcome of disparate treatment methods	SBU inquiries, governmental inquiries of healthcare organisation, procurement procedures	Literature discussing the New Public Management doctrine, policy documents regarding reorganisation of healthcare

Table 1. Schematic overview of the data collecting process

3.3.2 ANALYSING THE DATA

The *innovation process* has been the principal subject under scrutiny and the *microwave technology* the focal resource in the search for related interfaces. The overarching purpose of this thesis is to capture drivers and hindrances in the different settings of development, production and use for the innovation process of TUMT. Consequently, the *analytical unit* is *the interface*, between the microwave technology and other social and material resources.

Appropriating the 4R model to the analysing tool means that any observed resource is categorised into either one of the four resource types: products, facilities, business relationships and organisational units. As this is a case study on technological innovation, it contains such a large number of details that it could potentially have generated an almost infinite number of interfaces, for example, in each little technical detail, in such as changes in algorithms utilised to program the software of the microwave technology device, etc. However, since the purpose is to investigate a med-tech innovation process, from development to use, the search had to be limited to interfaces that were decisive for the progress or obstruction of the innovation process at large. An example of this is specific technical interfaces: the development of a new type of catheter (belonging to the microwave device) might have caused extra expenditures to the development, but was quite easy to overcome technically and is not of focal interest per se. However, taken all together, all these minor technological changes are significant to understand the character of the development taking place in a specific relationship between any two organisational units. Consequently, the analysis of the data deliberately does not discuss all detailed technological interfaces, but rather searches to keep the interfaces at a more general level, so as to make explicit the main features of the innovation process.

Identifying the interfaces through the lens of the 4R model was the first analytical step, the next step was to identify drivers and hindrances from the interfaces. Drivers originate from interfaces where the focal resource, the microwave technology, could become fully or partly embedded, thus resource interaction supporting its embedding into the specific setting (developing, producing or using). Hindrances originates from interfaces where the focal resource found difficulties or was rejected to become embedded. Furthermore, sometimes there is more than one interface supporting a specific driver or hindrance. In other situations, one single interface generated numerous hindrances. It happens as one interface can contain many different layers of in-

teraction. For example, the interface between a physician and a medical technology device can contain such features as skills of the physician to operate the device/performance of the device in relation to the specific physician; competing treatment procedures available at a specific clinic; other treatment procedures which the specific physician is more skilled to use or personal preferences of the patient who in turn is pushing for certain treatment alternatives. Likewise, some of the drivers and hindrances identified in the different settings of development, production and use might be similar to each other, however their similarity might make them even more intriguing since they derive from totally different resource interfaces. The various drivers and hindrances are presented and discussed in Chapters 8, 9 and 10.

3.4 PRIMARY SOURCES & OBSERVATION

Primary sources include mostly interviews, but also one observation. Many of the interviews were undertaken face to face, where I personally visited both the company ProstaLund on several occasions and the hospital departments and clinics when doing interviews.

INTERVIEWS

The major parts of the interviews were undertaken between fall 2006 and fall 2009. However, some complementary interviews were undertaken during 2010. A total of 47 interviews were undertaken with 29 different respondents (see Appendix I for further information). Many of the interviews were done face to face as it also brought an opportunity to visit the different hospitals and see the device and have an experience of the treatment environment above the actual interview. Interviews at the company ProstaLund, were also undertaken face to face and thus visited in different phases of the company's development[11]. The duration of the interviews ranged from one to three hours. The selection of respondents was done on the basis of their relationship to the technology, i.e., if they were users, developers, purchasers, producers or investors. In other words, they all represented resources with an interface towards the technology. The interviewees were identified either on referral or during the search for representatives within an identified organisational unit that had used the focal microwave technology.

[11] ProstaLund went through some major changes while this study was undertaken. It was first located in Lund with the funder and developer of the technology as CEO. In 2008, it went into bankruptcy and was restructured with new owners, new personnel and a new CEO. It then changed location from Lund to Uppsala.

The interview questions were guided by the 4R model. Since this study consciously searched for interfaces, the four resource typologies of products, facilities, organisational units and organisational relationships were utilised to structure the interviews. The interviews were based on semi-structured questions so as to allow the respondents to bring in new aspects and provide an opportunity to find new interfaces of importance. The interview guides were not strictly followed, but were a support to make sure all central topics were covered. The questions were also adapted to the person interviewed. Informants ranged from engineers at the company ProstaLund to nurses at a urology clinic or hospital executive mangers.

In most cases, the interviews were recorded, but as some of the respondents felt uncomfortable being recorded, I refrained from this practice during a few interviews. Being aware of the loss of data this might have caused, detailed notes were taken during the interviews that were transcribed immediately after the interview session was over in order to minimise data loss.

After the case was written, which will be presented in the upcoming chapter, some of the respondents read and validated parts of the case that were based on their information. They were not able to influence my interpretation of the data, but they had a chance to control 'hard facts', such as how many patients are treated at their clinic every year, or see to that treatment related complexities were described in a correct manner. The details are important because there are lots of medical technicalities related to a study like this.

Using interviews as a primary source of data can be hazardous, as facts risk being biased on one respondent's opinion of a specific course of events. However, to avoid such risks, at least two different sources have been interviewed for each occurrence investigated and/or supported with as much secondary data as possible (Eisenhardt & Graebner, 2007; Silverman, 2006). Furthermore, conducting a partly retrospective study can be difficult in that it primarily relies on the respondents' memory of the course of events. However, this risk was limited by the fact that some of the respondents were no longer employees of the using setting or the focal company; others had changed positions over the years. Some urologists in this study had even changed their minds and went from enthusiasts to opponents of the technology. Others had already retired when the interviews were made. This means that these respondents did not have much of a hidden agenda or other such incentives for answering in a certain manner.

OBSERVATION

One observation was undertaken with the expressed purpose of seeing microwave technology 'in action'. The interaction between patient, machine and physician was of interest to me in my effort to understand and make sense of the treatment process. Since treatment is, for physicians who use microwave technology, often routine work, it was necessary to conduct an observation to get closer to the practicality of a microwave treatment procedure. The situation observed had many times before been described to me and this was an opportunity to follow a process in person. Observing the usage of microwave technology brought an additional dimension to my understanding of the physicians' description of usage. Silverman (2005, p. 174) describes it as practical issues, which become more evident and clear through observations, since the data collected is dependent upon the context where it is born (Silverman, 2005, p. 47). The observation was helpful to create a more nuanced picture and a deeper understanding of the technical functions of, as well as the social interaction connected to, the studied treatment method which is difficult to grasp through interviews alone.

An ethnographic method was applied, which can be explained as fieldwork or observations in particular environments (Silverman, 2005, p. 49). Initially this method was adopted from anthropology by ethnographers and later became a sociological method used in studies of subcultures in real-life contexts through direct participation (Van Maanen, 1979). The observation undertaken during this study was performed without any electronic recording. Instead, the technique of field notes was used. Everyone participating in the study was aware of the fact that they were being observed as well as by whom. Each participant, a urologist, the patient and a nurse in the treatment room were also given a brief introduction as to why they were being observed.

3.4.1 SECONDARY SOURCES

As described above, secondary sources were necessary to fully understand the discourses and policies in each of these contexts, particularly the healthcare use context. Secondary sources were, especially initially, crucial to improving my basic knowledge and prepare for conducting interviews. Using academic journals and books, from both medicine and social sciences, public documents, policy documents, reports from government agencies but also from a local county level. To some degree, statistical information was used to grasp such data as the changes in microwave treatment frequency over the years this study spans. Likewise, the access to written material concerning the micro-

wave technology and treatment implications, from both the company and scientific sources, were important. Here below the written sources are described, which were used as first-hand written data.

PUBLIC DOCUMENTS

The documents cover central policy issues on innovation and healthcare policy, reports and central evaluations investigating the general treatment of BPH and specifically the efficiency of the microwave treatment. At a local level, documents covered a particular clinic's treatment policies for BPH, procurement documents, hospitals accounting data and reports on reorganisations within the counties and other such control documents. This information was crucial to grasp the basics behind tendering and procurement procedures, management accounting within the public sector and BPH treatment praxis in a general sense. These specific sources are referred to in the empirical chapter and found in the reference list under the heading "public inquiries, reports & digital documents and sources".

SCIENTIFIC JOURNALS AND BOOKS

The medical literature concerning the disease of BPH and other different available treatment therapies and their technical/medical implications and terminology was crucial to be able to follow the discussions with physicians and nurses during the interviews. The medical terms are indeed central knowledge to have before conducting interviews with physicians. Not only because it provides an ability to construct relevant follow-up questions during discussions and understand the answers, but it also gave the physicians the opportunity to give more comprehensive answers and describe treatment complexities in a more detailed manner, given that they understood that I could follow their arguments properly.

Another area of literature was within the NPM doctrine. This literature enabled a fuller picture of the healthcare context and explained managerial changes described in the interviews. All literature used, is referenced in the empirical chapters.

INDUSTRY REPORTS, PATENT REGISTERS, FINANCIAL NEWSPAPERS

These secondary sources were especially important to control the 'pre-history' of how the technology evolved and moved between different continents and the developing, producing and using settings before ending up in Sweden. The respondents from this period are few, simply because there were few persons occupied in the development of the technology during its early days in Sweden. Interviews sometimes provided slightly different information, such as the year a new version of the technology was launched, or which company that first had the patent. Being reliant on the memory of the respondents, old patent registers could, for example, provide information about who first patented the microwave technology in the US and the correct name of the specific company at the time. Furthermore, industry reports and to some degree even international financial magazines were as well helpful to detect the development path of the technology during the 1980s. All sources are referenced in the empirical chapters and gathered under the heading "public inquiries, reports & digital documents and sources" in the reference list.

The next part, Part III, describes the empirical material over the course of three chapters.

PART II. EMPIRICS

The empirical chapters present the case of microwave technology in the treatment of BPH. The first, Chapter 4, documents the technological development of microwaves and the emergence of the Swedish company producing the focal microwave technology, ProstaLund. Chapter 5 explores the usage environment and discusses the larger structural context of healthcare with regard to the organisation and regulations that shape the context of public healthcare. Chapter 6 continues the investigation of the usage context and showcase four 'mini cases' of different Swedish hospitals and the ways in which they assess new med-tech solutions at the systemic level and their embedding of this specific microwave technology at a specific level of use.

4. A MED-TECH INNOVATION FOR THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

One of the core questions in this empirical chapter concerns how the benefits and drawbacks of a technology both affect and are affected by the context in which it is brought into use. This chapter shall, therefore, follow the development of microwave radiation from its very first steps into the area of medicine and then consider its applications in urology. Step by step, we shall examine the development journey of microwave technology in the treatment of *Benign Prostatic Hyperplasia,* BPH.

4.1 A BRIEF BACKGROUND ON THE DEVELOPMENT OF MICROWAVE TECHNOLOGY – FROM DISCOVERY TO MEDICAL USE

The first application of microwaves in medicine was in 1938 (Schepps & Rosen, 2002), when used as an alternative to diathermy[12], as microwaves were found to be more focused and able to heat deep tissue without causing damage to the skin (Sobol & Tomiyasu, 2002). However, the applications in medicine took nearly a hundred years, microwaves were discovered in 1864 and their use and areas of applications have since then spread to many different contexts. From microwave ovens and catching speeding drivers on the highway, to high-tech devices in medicine and telecommunication, the applications of microwave technology are numerous and range from everyday appliances to more advanced scientific applications (Sorrentino et al., 2002; Sobol & Tomiyasu, 2002; Schepps & Rosen, 2002).

The first laser used in medical applications was constructed in 1954 and, since laser is a stream of coherent microwaves, it was initially named Maser! Jumping forward to the 1970s, microwaves were being used in the treatment of uterine cancer (Wust et al., 2002). It was not a widespread treatment at the time and most treatments were undertaken in the U.S., even though the technology and method was known to the medical community worldwide (Bolmsjö, 2006).

A few years after the introduction of microwaves in uterine cancer treatment, Israeli researchers[13] initiated trials on the use of microwaves to treat minor prostate trouble. At the beginning of the 1980s, the Israeli team had further developed their project and presented a study where microwaves were used in the treatment of BPH (Yerushalmi, Servadio, Leib, Fishelovitz, Rokowsky & Stein, 1982). The research team had developed a device that was based on the same principles as had been used in the treatment of uterine cancer. Basically, the new device destroyed excessive tissue in tumours through heat produced by microwave irradiation (Ibid).

There was more than one company producing microwave technology for the treatment of BPH in the early years of the 1980s (Bolmsjö, 2010). The company, Biodan, is thought to have been both the first and largest supplier of microwave equipment at the time (Bolmsjö, 2009; Wagrell, 2005). The

[12] High-frequency electromagnetic currents that heats tissue, utilised in surgical procedures
[13] The research team belonged to different research institutions and departments; The Weizmann Institute of Science, The Kaplan hospital (Rehovot, Israel) and Beilinson Medical Center (Petah Tiqva, Israel)

company was located in the Netherlands, yet managed from Israel (Bolmsjö, 2010). During the first half of the decade, the method slowly spread in Europe, despite a certain scepticism among urologists (Norlén, 2007; Pedersen, 2007). Urologists were suspicious of the new method, sticking with the dominant surgical procedures of the time, which limited the spread of the technology in Europe. Except for one country that was open to new solutions: Italy (Bolmsjö, 2010; Pedersen, 2007; Norlén, 2007; Carringer, 2007), which was known as a test market for new medical technologies in the 1980s (Bolmsjö, 2006). Biodan consequently sold machines in Italy, where microwaves slowly achieved widespread use in the treatment of BPH. Given the surge of interest in microwave technology, Italian producers of medical devices were enticed to enter the business. At the peak of the TUMT (*Trans-Urethral Micro Themotherapy)* boost in Italy, an Italian medical technology producer, with a CEO named Grondelli, contacted a Swedish radio physicist, Bolmsjö, to assist in his hunt for a microwave machine to treat BPH. Bolmsjö, who was running a small, one-man consultancy firm in the south of Sweden, agreed to construct such a machine for his Italian customer. Grondelli was very pleased with the outcome and requested to extend the contract. The Swedish producer was, however, not interested in any prolongation as he had a number of other, more attractive projects at hand.

The Swedish-Italian product was called 'ProstaLund Macchina' – *macchina* being the Italian word for 'machine'. An amusing detail in the story is that several 'ProstaLund Macchina' were sold in Italy in the late 1980s. These machines were not produced by Bolmsjö, the Swedish producer, though the Italian customer still kept the name, because of its 'exotic feel'. What Grondelli didn't know then, was that there would come to be a large number of ProstaLund machines, but much later and in a somewhat technically modified version.

The story outlined above, of the microwave's journey into the area of medicine and the very first BPH device, accounts for only the first few steps of the long innovation journey of microwave treatment for BPH. Subsequent sections will pay close attention to the technology's entrance into further development, production and use in Sweden. As we shall discover later in the story, it was neither technological novelty nor the endeavour of commercial production that were the main initial incentives behind this project. On the surface, it seems like a quite typical development story, which it is in some ways. However, there are many more aspects to this innovation journey than commercial incentives.

4.1.1 MICROWAVE TECHNOLOGY'S INTERNATIONAL DEVELOPMENT JOURNEY

Microwave technology struggled to find users in Europe in the early 1980s. Without any larger success, instead the technology did spread to the U.S. North Americans started their first proper treatments with the technology a few years after the Italians and, in the hands of U.S. urologists, the technology was further developed. For the time being, microwaves provided a rather basic and standardised treatment procedure. The technology provided an anal catheter that functioned as a 'delivery device' for microwaves and the procedure was about the same for all patients except for relatively small differences in the length of the treatment procedure.

The first significant change was the addition of a second catheter running through the urethra. An American urologist named Turner came up with the idea of adding an extra catheter to protect the urethra from heat damage during treatment[14] (Patent - US 4967765A). It turned out to be an important moderation as the new catheter radically enhanced treatment results. A U.S. medical technology producer, BSD, shortly thereafter launched a microwave machine with a double catheter. This machine was primarily sold in South America in the second half of the 1980s. In 1997, BSD then sold its double-catheter technology to the company TherMatrx, yet with BSD owning 30% of the company (Bolmsjö, 2009). The technology was not FDA-approved when it was sold to TherMatrx, which explains why BSD had chosen to sell the technology in South America and not the U.S. TherMatrx eventually succeeded in getting an FDA permit, but not until 2001 when they were able to provide the FDA with a three-year follow-up study.

The first TUMT-device to receive FDA approval was produced by the French med-tech company, EDAP Technomed, that got their first version approved in 1996 and the second, including a bladder neck catheter, was approved in 1997. The reimbursement[15] level for microwave treatment was rather high in the US (Lotan, Cadeddu, Roherborn & Stage, 2004).

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[14] Since the prostate is a small gland that surrounds the urethra, when put under high irradiation that causes heat in the prostate tissue, the procedure can cause heat damage to surrounding tissue, such as the urethra. A damaged urethra could lengthen recovery time and cause unnecessary suffering for the patient and difficulties with urination.

[15] *Reimbursement* is the payment healthcare providers in the United States receive from insurance companies for performed treatments. Each treatment has a national rate of reimbursement. The level of reimbursement is set by the governmental agency, CMS. In 2007, the reimbursement rate for TUMT was 4,427 US dollars performed in outpatient office and 552 US dollars in surgical in-patient premises. In the US new technologies are reimbursed with favourable quotas in order to promote new technologies in the system. Normally, the level of reimburse-

As a result of the FDA approval (which commonly has the status of a hallmark for med-tech devices) EDAP Technomed decided that the time had come to treat all European men suffering from BPH with microwaves. However, EDAP had been developing their TUMT device since the late 1980s and the first device was launched in Europe in 1990. This was a machine called *Prostatron*; physically, it was a huge machine but, by the standards of 1990, it was considered very 'high-tech', having as it did a computer screen and advanced technological equipment (Pedersen, 2007). EDAP Technomed put considerable effort into the marketing of their new device; for instance, before the launch of the ProstaTron, urologists from all over Europe were flown in to the company's headquarters in Lyon to learn more about the new method.

One of the urologists visiting Lyon, who was potentially interested in acquiring a device, was the Swedish urologist, Pedersen, from Örebro University Hospital. Pedersen was intrigued by the new technology and seemed most likely to become a user. However, in the end, the acquisition was thought to be too expensive; one machine represented an investment of 1 million SEK – about 120,000 USD, which at the time was a considerable investment. In addition, each treatment amounted to another 600 USD. In comparison with the standard treatment of BPH – minimally invasive surgery at a cost of 1,600 USD per treatment – microwaves were an expensive investment. For a public hospital under economic constraints, it simply was too large an investment to make. The economic argument was that, once the investment in the technology was made, each treatment would be less costly. However, as Örebro University Hospital already had surgical premises, the 'facility investment' for the standard surgical procedure was already in place. Any investment in a ProstaTron device would consequently constitute an additional facility investment for a disease that had an existing procedure, including facility investments, already in place (Pedersen, 2007; Bolmsjö, 2003; Carringer, 2007).

4.1.2 NEW CONDITIONS IN HEALTHCARE PRACTICE

The chief urologist from Örebro University Hospital, Pedersen, that visited Lyon after an invitation from EDAP advocated a purchase of the Prostatron device because it could potentially lower the costs of BPH treatment at his

ment is dependent on many factors, such as relapse time, post-treatment complications, treatment time and full recovery rates to mention but a few. Another decisive factor is the age of the technology. In order to facilitate new technologies entering the system, the most recent technologies normally have a high rate of reimbursement that declines over time (Lotan, Cadeddu, Roherborn & Stage, 2004).

clinic. The problem was that there were no financial means to make such a purchase (Pedersen, 2007; Carringer, 2007). Pedersen had many reasons for wanting this machine. Not only was he driven by the excitement of having a new high-tech device that could put the clinic at the forefront of treatment methods, but also this technology could offer potential economic advantages in comparison to already existing surgical methods.

Also, the economic aspect was an increasingly pressing issue at the clinic, fuelled by structural changes in Swedish hospitals. In fact, a reorganisation of the whole healthcare sector had made economic aspects of treatment more important than ever before to physicians as well. The heads of clinics, with ultimate budget responsibility, were now held accountable for treatment costs, which was not the case before the reform. This fundamental change of the healthcare system thus constituted an important driver for managers and physicians to search for new, cost-efficient methods.

The organisational change at public hospitals at the beginning of the 1990s was significant for the nascent move towards 'efficient technology' among physicians (Malmberg, 2010; Norlén, 2007; Pedersen, 2007). Therefore, underlying Pedersen's action, was the reorganisation of the Swedish healthcare system that was pushing for more economical alternatives in treatment. The reform originated from the wider change in management of Swedish public institutions (Pollitt & Bouckaert, 2004; Hood, 1991; Agevall, 2005). What Pedersen was dealing with was the effects of a general reform that had altered the managerial prerequisites of public institutions. This shift is commonly referred to as *New Public Management,* or NPM. The wide-ranging scope of NPM had been under development in public organisations since before 1988 (Blomgren, 1999, p. 54) and at the beginning of 1990, physicians working at larger hospitals stated that they had started to feel the consequences of the new rules pervading public healthcare. The economic dimension, such as accountability for the cost of treatment, became perceptible directly in practice (Pedersen, 2007; Norlén, 2007; Häggman, 2006; Malmberg, 2010a). To better grasp what happened next and how the technology ultimately ended up at the urology clinic in Örebro, the next section will briefly describe the basics of the NPM reform's application in Sweden's healthcare system as a way to grasp how it affected the development of the first Swedish TUMT device.

4.2 NEW PUBLIC MANAGEMENT TRIGGERS THE INITIATION OF TUMT DEVELOPMENT IN SWEDISH HEALTHCARE

New Public Management refers to the management reform that shaped the public sectors of most OECD countries in the 1980s and 1990s (Öhrming, 2008; Sahlin-Andersson & Engwall, 2002)[16]. There are several ways to interpret and understand the changes entailed by this reform. However, what is certain is the quite radical alterations it caused in the governance of public institutions. This section shall therefore account for the most significant tenets and objectives underlying the NPM reform as to grasp how it has affected the development and use of TUMT.

NPM should, first of all, be understood as a 'parachute designation', which applies principles derived from market models that aim to organise public institutions in a more efficient way. However, there are no specific concepts or properties in the NPM doctrine[17].

The incentive behind the application of the private sector's presumed market organisation was the reversal of two of the fundamental doctrines of the preceding system of public administration, PPA[18]: First, *the distinct separation between private and public* and, secondly, *a shift from process accountability towards accountability by results* (Abrahamsson & Agevall, 2009; Öhrming, 2008; Hasselbladh, Bejrot & Gustavsson, 2008). Whereas PPA practised process accounting and was organised according to the 'larger bureaucratic system's logic', the NPM reform converted to goal-orientated accounting, so that responsibility for economic results became decentralised in the organisation (Blomqvist, 2004; Öhrming, 2008). In the scholarly debate, the market-orientated characteristics of the reform have been referred to in many different ways, such as "quasi markets" (Blomqvist, 2007; Almqvist, 2006; Foss Hansen, 2011) or "market–orientated", or "attempts at free-market

[16] For further reading, see also: Hood, 1991, Hood, 1995a, Hood, 1995b, Christensen & Laegreid, 2003

[17] Similar patterns can be observed in the different countries where NPM has been applied but there is no set formula for the implementation or results of NPM. It is not only a question of *which concepts* are adopted, but equally *country-specific contexts* are acknowledged to be a decisive factor in the outcome of the application of the reform (Pollitt & Bouckeart, 2004). Thus, the pervasiveness of different currents within NPM varies and is highly dependent on domestic socio-economic forces and prerequisites (such as political climate, culture, and the earlier condition of public institutions) within each specific country (Almqvist, 2006, Pollitt & Bouckaert, 2004, Hood, 1991, Christensen & Laegreid, 2007).

[18] PPA, Progressive Public Administration – the system preceding NPM, characterised by a split between public and private as well as its unambiguous rules preventing the corruption of public servants and politicians (Hood, 1995; Almquist, 2006).

thoughts". Regardless of whatever denotation was applied to describe the construction of a market in public institutions, the actual effect and its efficiency in public institutions, have been subject to a far-reaching scholarly debate in many different academic disciplines (Hall, 2007; Forsell, 1999; Elzinga, 2012; Almqvist, 2006; Blomqvist, 2004; Agevall, 2005; Hasselblad et al., 2008)[19].

Before the NPM reforms, Swedish public administration was accused of being overly bureaucratic, thus causing organisational inertia. Consequently, when the political climate changed in the 1980s, traditional central planning was dominant and a new neo-liberal outlook brought forth the ideals of free markets. Concepts such as "market mechanisms" and "competitiveness" were then automatically adopted[20] (Almqvist, 2006; Blomqvist, 2007). The introduction of market models was supposed to invite private actors to handle the provision of services, which it did in most countries (Öhrming, 2008; Hall, 2007). However, the Swedish application of NPM was more characterised by its high degree of decentralisation, rather than privatisation[21] (Byrkjeflot & Neby, 2008). A result of the decentralisation in healthcare was the initially quite scattered application of the new reform, which was due to the high variation between the 20 Swedish counties. The decentralised counties created a national healthcare market without necessarily enhancing privatisation. One out of several new important mechanisms in the system was the internal pricing of health services. Each county thus played an important role in upholding the market in the new system. Counties created pricelists for care and were able to debit patients from other counties with higher tariffs than their own 'in-county' patients. Today, a couple of decades later, the pricelists are increasingly standardised on a national level. Decentralisation was thus a first attempt to mimic the market ideal on a national level, and it also explains the variations between the Swedish counties in provided care, prices and management of care production. Despite the variation between hospitals and counties, there are some general traits in the NPM doctrine. Before we go into a brief discussion of those general features to see how they manifest themselves in the hospital organisation, let us consider a schematic picture (Figure 3) of these pivotal concepts (picture revised from Mårten Øgård, 2005).

[19] The very same traits have been recognised internationally as well, for example, see: (Christensen & Laegreid, 2011; Christensen & Laegreid, 2007; Hood, 1995a; Evetts, 2009; Baldersheim & Rose, 2000; Pollitt & Bouckaert, 2004, Jensen, 2004).

[20] The same traits are visible in other countries as well and have been discussed amongst international scholars, for example see: Christensen & Laegreid, 2007; Pollitt & Bouckaert, 2004 pp. 187-88; Hood, 1991, p. 5

[21] As an example, in France and the UK, fewer than 50% of public servants were centrally employed while, in Sweden, the corresponding number was only 17.3% in 1994 (Pollit & Bouckaert 2004; Culyer & Wagstaff, 1993)

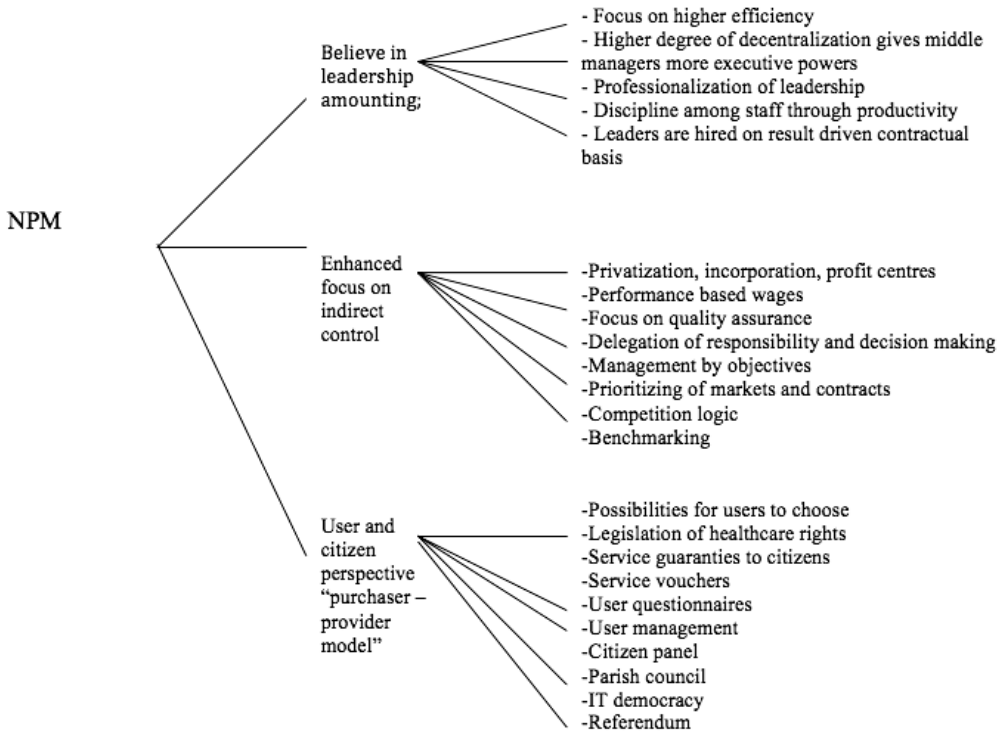

Figure 1. Common traits in the reorganisation of public healthcare in Sweden

If the market ideal is central to the reform, the features outlined above in Figure 3 are based on such ideals. Furthermore, these are the most general and significant attributes of the reform but, then again, there are variations between the Swedish counties with regard to interpretation and strategies for how to use provided tools. Some regions have embraced organisational measures referred to as 'lean production'[22], in order to enhance efficiency (Christensen, 2009). Others have acceded to the competitive aspects by trying to attract as many patients as possible from other counties (Beckman-Suurküla, 2007).

Another consequence of the new organisational rationale is that responsibility has moved downwards in the organisation. Physicians are held accountable

[22] Lean production, as interpreted in most health care contexts, in this case referring to Skåne region, is not equivalent to the concept of "lean production" as referred to in business administration literature (Womak & Jones, 1994; Womak & Jones, 2003). Yet, public healthcare organisations themselves refer to their reorganisations as 'lean production'.

for the economic outcome of their treatments. Thus, clinics have become profitable units and management incentives are more focussed on economic variables (Hasselbladh et al., 2008; Öhrming, 2008). As a consequence, hospital organisation is characterised by high independency in terms of performing activities within the smaller units as long as the units keep within budgetary targets (Almqvist, 2006; Anell, 2010). There is also increased flexibility in areas such as hiring personnel and fewer restraints on systems of reward. However, in this system, retrospective evaluations and regulations are important tools for politicians and managers (Bejerot & Hasselbladh, 2008). In Sweden, the decentralised healthcare system is governed by local county councils led by politicians. Given that politicians are unable to monitor production processes as they occur, i.e., the decentralised profit units, the demand for regulations in practice is greater. Retrospective evaluations then fulfil the function of controlling whether regulations have been properly followed (Vedung, 2004). *Practice* is thus, to a greater extent, bound to contracting and regulations. Accountability of smaller units and comprehensive and detailed regulations are new important tools in monitoring decentralised healthcare (Vedung, 2004; Almqvist, 2006; Agevall, 2005).

The extensive accountability of smaller units then formalises the economic aspect of all activities undertaken in profit units, such as, for instance, clinics (Hasselbladh et al., 2008; Almqvist, 2006). Whether the financial aspect has become superior or subordinate to the 'pure functionality aspects' of therapeutic treatment is contested. However, a quite clear result of the far-reaching accountability is reduced scope for professional expertise in practise (Öhrming, 2008, pp. 255-268). The shift made a notable difference to employees in healthcare organisations, and this is well illustrated in practise, as stated by the head of the central purchasing department in Uppsala County;

> *"Earlier watchwords in our organisation were nurturance and adaptation to existing needs. Today those words have been altered, including one word: competition"* (Södergren, 2005)

The increased focus on economic aspects was noticeable, even for physicians in the early 1990s. Hospitals were struggling to reorganise their activities in line with the new directions. Rationalisations through budgetary constraints and cutbacks were common currency in public healthcare in the early 1990s (Pedersen, 2007; Norlén, 2007). Yet, despite economic constraints, activities had to continue at a normal pace, thus production of healthcare services was

not lowered. Clinics strived to find new solutions for handling their stringent economy and, therefore, put faith in new technological solutions (Pedersen, 2007; Norlén, 2007; Malmberg, 2010a).

Urologists witness that it was easier to adopt new technology back then, in the late 1980s early 1990s, since the requirements for scientific documentation normally were lower than those of today (Norlén, 2007; Malmberg, 2010a). Across the different surgical specialities, the new public management resulted in a novel interest in alternatives to invasive surgery. Several of the new technologies at the time were minimally invasive techniques, such as laser and microwave, aimed at replacing invasive surgical procedures (Norlén, 2007; Pedersen, 2007; Schelin, 2010; Bolmsjö, 2009, p. 17; Malmberg, 2010a).

In these early days (beginning of the 1990s) of the NPM system (beginning in the 1990s), the regulations and scientific documentation were not yet systematised in the way they are today, which is why a hostile debate of the usefulness of microwave treatment in BPH flourished among urologists (Norlén, 2007). In this debate, many of the larger research hospitals accused the smaller hospitals of an excessively lax attitude towards new technology and for 'marketing' new methods lacking results with scientific significance (Norlén, 2007).

High-tech solutions were, from the physicians' perspective, supposed to increase capacity and lower costs, even though one problem remained: scientific documentation to verify the effectiveness of new methods. Ordinarily, obtaining scientific documentation is expensive and time-consuming (Malmberg, 2010a; Wagrell, 2010; Schelin, 2010). However, it has been claimed that, at the beginning of the 1990s, there was an over-confidence in what new technology could achieve in terms of enhancing treatment efficiency (Norlén, 2006; Pedersen, 2007; Malmberg, 2010a). But, at the same time as clinics searched for economic efficiency through new high-tech solutions, there was poor economic capacity in healthcare organisations to conduct scientific trials and establish new methods (Pedersen, 2007; Carringer, 2008; Malmberg, 2010a). Technological solutions were often supposed to *replace* old methods, so as to achieve the highest efficiency in production. The idea of having many treatment methods alongside each other was seen as inefficient within the new NPM doctrine; either-or was the only way to go from an efficiency point of view.

4.3 MICROWAVES IN THE TREATMENT OF BPH

The new organisational structure of healthcare initially brought many new challenges for physicians, such as incorporating economic perspectives on treatment procedures. What kinds of benefits could the microwave-based technology then offer, which already available treatment methods in the treatment of BPH could not?

BPH is a benign enlargement of the prostate prevalent in *ageing* males (McNeil, 1978, Barry,1990, Brandy, 1971). The prostate is a small gland that surrounds the urethra, located just underneath the urine bladder (see fig. 4). As the prostate grows throughout a lifetime, it can come to obstruct normal urinal flow through the urethra and can also disturb normal emptying of the bladder.

Common symptoms include difficulties in urinating, ranging widely in severity. In men between 31 and 50 years of age, the time span for an approximate doubling of the prostate in size is 4.5 years while, after 50, the time is ten years (Schelin, 2006; Blandy, 1971; Garraway, Lee & Collins, 1991; Barry, 1990). BPH is not considered a lethal disease, even though, in some rare cases, the condition creates a state where urine flows back from the bladder to the kidneys, which, without treatment, could be life-threatening. The most common symptoms of BPH are urinary urgency, incomplete emptying of the bladder, weak urinary stream, hesitancy and impotence (Barry et. al 1992; SBU, 2011). Even though more or less all men over 50 will experience troubles caused by an enlarged prostate, far from all will need treatment for their symptoms. Approximately 50% are treated for BPH symptoms, and within this group there is a variety in the severity of symptoms and treatment needs (Garraway et al., 1991; Schelin, 2006).

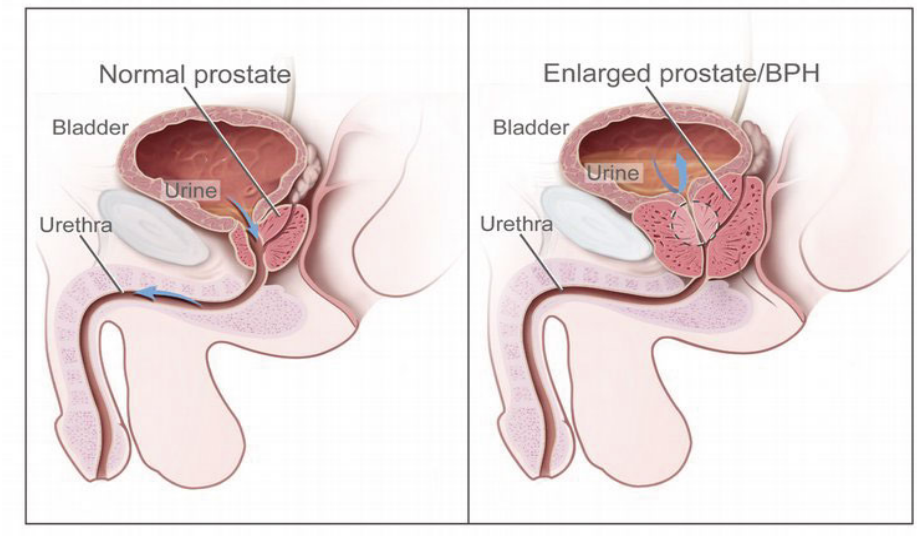

Figure 2. Anatomic cross section of normal prostate (left) & an enlarged prostate (right).

Efficient treatment options are desirable due to the high prevalence of BPH. Expenditure for institutional care of BPH amounted to 160 million SEK in 2008, whereas policlinical care of BPH amounted to another 60 million SEK, and the total social costs were approximately 140 million SEK – the latter two numbers annualised to the 2009 cost index (SBU, 2011, p.99). Thus, a total cost of 360 million SEK of BPH treatment in Sweden.

Since the early 1990s, new pharmaceutical treatment options have played a decisive role in the development of BPH treatment. The advent of new pharmacological alternatives, called alpha-blockers, altered the prerequisites for therapeutic treatment. Medication was in widespread use in Swedish healthcare around 1992 (SBU, 2011). The different types of alpha-blockers[23] relieve the symptoms of BPH, but do not cure patients. As long as patients continue with medication, their symptoms commonly will disappear or significantly diminish. A two-week course of alpha-blockers, therefore, will not cure the disease. Conversely, medication is a long-term continuous treatment to combat symptoms. If symptoms persist in spite of pharmaceutical therapy,

[23] That is, a 5-alpha-reductase inhibitor, which reduces the pace of growth and reduces the volume of the prostate and alpha-1-blocker, which reduces the tone of smooth muscle surrounding the urethra and improves urine flow (Wagrell, 1999).

invasive treatment is required. Invasive treatment methods are surgery or minimally invasive alternatives, such as microwave treatment[24]. Nevertheless, the use of pharmacological treatment of BPH in Sweden was already widespread in 1992. In 2006, about 115,000 men in Sweden were assigned pharmacological treatment. Between 12,000 and 16,000 men enter pharmacological treatment each year, and about the same number stops treatment due to adverse side effects (SBU, 2011).

As regards the surgical treatment of BPH, it has experienced a decline due to enhanced use of pharmaceuticals. However, surgical treatment had, already in the 1970s, made great progress. The earlier method of invasive surgery through open incision, *open prostatectomy*, was replaced by minimally invasive surgical methods applying laparoscopic technology (commonly referred to as *keyhole surgery*) called *Transurethral resection of the prostate*, abbreviated to TURP (Schelin, 2006 pp. 24-25; Wagrell, 1999, pp.12-13; SBU, 2011). Keyhole surgery is generally less strenuous on patients than open incision, and thus renders a more efficient treatment for both the healthcare system and patients.

Consequently, the 'gold standard' treatment has been TURP since its introduction. This surgical procedure reduces tissue through a planing technique, using a small scalpel that is inserted into the body with the laparoscopic method. Patients respond well to the treatment, with good recovery results and fairly low readmission rates (Hoffmann, McDonald, Monga & Wilt, 2004). Treatment requires institutional aftercare for two or three days after intervention. This surgical treatment can be painful for patients, especially in the immediate aftermath of surgery, and requires a surgeon with a dexterous hand[25]. The typical patient that undergoes this surgery is over 50 years of age, however, the risks of surgery increases with age and older patients are unable to undergo surgery.

On the contrary, the basic principle of microwave treatment is to destroy excess tissue through the heat produced by microwave radiation. The common

[24] Other, less common current treatments are: TUVP, TransUrethral Vaporization of the Prostate, utilizes the heat from high-voltage electric current which ablates obstructive prostatic tissue and seals the surrounding blood vessels. TUIP, Trans Urethral Incision of the Prostate is a procedure utilising a combined visual and surgical instrument (resectoscope) is inserted through urethra, KTP-Laser (commonly known as 'green laser') and HoLEP, Holmium laser enucleation of the prostate is a minimally invasive treatment where the patient is under general anaesthesia, the surgeon uses the laser to enucleate the prostate gland tissue.
(SBU, 2011).

[25] The prostate is as small as a walnut and located around the urethra. The surgical operation requires precision down to millimetres, which is why, when performed by hand, it is associated with a higher risk of damage and requires great skill from the surgeon.

name for microwave technology in the treatment of BPH is *Trans Urethral Micro Thermotherapy* (abbreviated TUMT). Microwaves make tissue wither under radiation, leaving the bladder and urethra with normal urinal flow. Since no tissue is removed, treatment creates parts of necrosis in the prostate gland, making the healing process somewhat longer than for surgical treatment, where tissue is directly or mechanically removed (Jepsen & Bruskewitz 1998, Oesterling, 1995). However, even if longer, the healing process is more merciful after microwave treatment in the sense that patients normally are back to work one day after treatment. Follow-up studies show that TUMT is an effective and gentle treatment method, but the surgical method of TURP is generally involved with fewer subsequent BPH treatments and larger improvements of symptoms by comparison to TUMT (Hoffman et al., 2004)

TUMT was the 'hot' technology in BPH therapy in the early 1990s (Norlén, 2007; Malmberg, 2010a), offering a policlinic treatment without the standard surgical implications or hospitalisation and aftercare. Hospitals could thus potentially make great savings by replacing surgery with microwave treatment, which also meant that surgery hours could be liberated from an already pressed schedule. There were also potential savings in terms of anaesthesia and aftercare expenditures. Also, TUMT seemed more patient-friendly, when no surgery was involved patients could return to their normal lives within a couple of days. Consequently, when first introduced, microwave treatment seemed a very promising alternative to the laparoscopic surgery method, TURP (Bolmsjö, 2006; Wagrell, 2007; Pedersen, 2007). The benefits that TUMT could potentially offer both patients, as well as healthcare, laid the foundation for the fast-growing interest in the new technology among urology departments in Sweden, especially so against the background of the new management principles introduced with the NPM reform (Malmberg, 2010a; Pedersen, 2007; Norlén, 2007).

4.3.1 ÖREBRO & PROSTALUND – DEVELOPING A SWEDISH TUMT TECHNOLOGY

No wonder, then, the urology department at Örebro University Hospital (USÖ) wanted a TUMT device, caught as it was in a pressing economic situation with a potential solution at hand. How, then, did this urology department follow through with a purchase of microwave technology?

After Pedersen's visit to Lyon, the determination to use TUMT treatment in the department in Örebro was even stronger. But, instead of buying

the French Prostatron, the department decided to develop its own device. Initiating discussions with a medical technician at USÖ – a man named Roos with special proficiency in microwave technology – the two of them examined the possibilities of developing a TUMT device at the hospital. At this point, the previous experience from manufacturing the ProstaLund Macchina, became relevant again. Given the rather small world of medical technicians, Roos and Bolmsjö – the man behind the ProstaLund microwave device – already knew each other from prior professional encounters. Bolmsjö and USÖ ended up in an agreement mediated through public technology procurement. ProstaLund was funded by public means, and the hospital department earned treatment royalty over the next few years, following the project's beginning in the early 1990s (Pedersen, 2007; Bolmsjö, 2010; Bolmsjö, 2005; Bolmsjö, 2009, p.20).

The technical development lasted for two years, and the team turned out to contain a somewhat beneficial combination of knowledge and resources. Bolmsjö's competencies comprised previous understanding of the specific technical construction, and he provided the necessary facilities in which they could undertake the construction of the machine. Roos contributed his special competence in microwave radiation and Pedersen performed continuous clinical testing during development (Pedersen, 2007; Bolmsjö, 2006).

In 1991, the device for USÖ was ready to be brought into use and it was the first all-Swedish-produced TUMT machine. It had the same basic functions as the ProstaTron, launched in the European market a year before, but with a few differences in technical details. One of the problems identified in the use of the ProstaTron had been the control of pain for patients, which was related to temperature regulation. The ProstaTron had a regulator system that turned off the machine as soon as the temperature exceeded a certain level. The heat development in the prostate tissue was slightly too fast in relation to the modulator, which caused pain for the patients; after this, the modulator immediately switched the machine off and treatment had to be resumed from the beginning. In the Örebro ProstaLund TUMT construction, the catheter was equipped with a cooling system so that temperature did not rise above 44 degrees Celsius in the rectal area, whilst the intra-prostatic temperature reached a maximum level of 50 degrees Celsius. In this respect, the ProstaLund-Örebro device could benefit from prior knowledge and experiences from development, knowledge embedded in Bolmsjö's small consultancy firm in Lund and, as a consequence the new 'Swedish' TUMT-device, was slightly more technically advanced in comparison to the first generation of TUMT devices (Pedersen, 2007; Wagrell, 2007; Bolmsjö, 2010).

When entering the development project, Bolmsjö had been running a small consultancy firm in Lund, taking on various projects ranging from space science to medical technology. The firm was, at the time of the TUMT development, named Lund Instruments. However, the two-year-long project with Örebro did leave a lasting impact on the business. In order to measure up to continuously new circumstances in technical features and clinical data that occurred as the project proceeded, the small workshop had no choice but to technically evolve. In small steps, new considerations demanded new skills and specialised knowledge.

Since Bolmsjö's last encounter with the TUMT device, there had been both technological and methodological progress. After a world tour from Italy to the USA, South America and France, the TUMT technology had developed new features in both its physical attributes and therapeutic use during this journey. For example, the device was now equipped with a computer screen and more modern technical functions and one large change was the urethral catheter. Thus, due to a continuous development of the technology - propelled by direct users discovering deficiencies and finding new ways to enhance the treatment - there were new technological conditions in the construction of the TUMT device. Even if the technical logic behind its construction was equivalent with the first device constructed by Bolmsjö, this new version of TUMT was a substantially different device. In order to meet the new, more technically advanced, requirements, Bolmsjö had to establish new contacts with different subcontractors (Bolmsjö, 2005, 2010; Pedersen, 2007).

After two years of development, the machine was brought into use at the Örebro urology department and it was assumed the project would continue as a clinical research project at the department. An agreement between Lund Instruments and USÖ provided some royalties to the department that, in turn, committed it to conduct clinical studies on the method and publish the results. However, financial difficulties put an end to the clinical testing of TUMT in 1992, as the budget was scarce. Lacking the financial means, the department was unable to employ any new assistant physicians, while the ordinary staff did not have enough time to proceed with the clinical studies. The provision of healthcare was more imperative at USÖ; to make sure everyday activities proceeded according to targets. Pedersen, who had initiated the project, then had more urgent obligations in the provision of care. The department hospital continued to treat patients with its machine, even if the cooperation between the parties had ended and clinical studies had to be interrupted (Pedersen, 2007; Bolmsjö, 2006; Carringer, 2007).

4.4 CREATION OF A NEW COMPANY: PROSTALUND AND THE RISE AND FALL OF THE TUMT TECHNOLOGY

During the development of its TUMT device, the small consultancy firm Lund Instruments had to contract new sub-suppliers, it had changed its physical facility structure, and had acquired new customers. While developing the machine, the interest in microwave treatment had escalated around the world. According to many, this was thanks to large marketing efforts by EDAP of its Prostatron device (Wagrell, 2007; Malmberg, 2010a; Pedersen, 2007; Norlén, 2007). Rumours of the ongoing development project in Sweden had spread, and customers called and faxed in orders to purchase TUMT devices from Lund Instruments. The expansion of production was fast and Lund Instruments now started its transformation from being a small consultancy firm towards becoming a small medical technology producer – a TUMT producer named ProstaLund. Between the years 1991 and 1995, the company expanded from one employee to 10 employees due to high demand (Bolmsjö, 2003). In 1995, there was a decline in sales, but use was still at a high level and turnover peaked in 1994-95, when it reached 20 million SEK. ProstaLund sold a total of 80 machines in Russia, Sweden and China between the years 1992 and 1996. The cost of a PL machine in 1995 was 2 million SEK, and charges reached 1,500-2,000 SEK per treatment. The same catheter could be used 20 times (Bolmsjö, 2005).

However, while ProstaLund experienced good sales and business was thriving; Swedish urologists had already commenced abandoning the method. There was a lot of scepticism against the method and too many bad treatment results – some with rather serious complications – but commonly there was no effect at all; patients that had been treated with microwaves still experienced the same kind of trouble as before. These consequences of treatment appeared universal for all microwave technologies available at the time, as there was little discrepancy in outcome of treatment amongst the different producer's devices. An additional obstacle was the lack of scientific data. It was accordingly no surprise when sales declined for ProstaLund in 1996. Use had been low since 1993 and, in 1996, it was almost non-existent among Swedish users (Bolmsjö, 2006; Schelin, 2010; Wagrell, 2004; Malmberg, 2010a; Pedersen, 2007). By the end of 1997, most companies involved in microwave treatment for BPH had gone out of business. The technology died off. What happened?

TUMT was, as was much new medical technology at the time, understood as a tool for rationalisation. Behind the logic of this rationalisation were

the collective expectations of the new technology's capacity to *replace* existing treatment and thereby lower costs (Pedersen, 2007; Norlén, 2007; Malmberg, 2010a). Such expectations assume that clinical testing is performed and evaluated compared to an already existing treatment. TUMT was embraced as the substitute to surgery and was evaluated on the basis of surgical standards. Why, then, was TUMT unable to replace the surgical treatment of TURP?

When TUMT was first introduced, the machines were technologically and methodologically unsophisticated. Some early users have described them as computers providing data that was difficult to interpret. But, at the same time, the treatment the machine provided was too standardised. The user functions were perceived as rigid and technically difficult and the patient-related functions were instead static. The technology provided a treatment referred to by some as a 'plug-and-play' methodology with no possibility to adapt a treatment session to the individual patient's needs (Carringer, 2007, Rosén, 2009).

One challenge of microwave treatment is measuring the intra-prostatic temperature. Deficiencies in temperature measurements were thus the major reason behind the 'plug-and-play' tag for the standardised treatment offered by TUMT. The TUMT machine measured the temperature in surrounding organs and in tissue not affected by microwaves and then used that data to approximate the intra-prostatic temperature. The temperature has to be at a level where the microwaves are actually able to destroy excess tissue *without* causing damage to organs located near the prostate (Rosen et al., 2002). For physicians to interpret that data and adjust microwave strength to achieve the correct strength of radiation for each specific patient was almost impossible with this kind of device. The results were often either too little tissue destruction or too much heat, causing damage to related areas[26]. Since temperature indications were rather ambiguous, microwave strength and treatment time were more-or-less fixed parameters, for example 60W, for 60 minutes. The downside of having fixed parameters was thus the inflexibility in treatment. This oversimplification of treatment generated the 'plug-and-play' metaphor, where physicians 'placed the catheter and switched on microwave radiation', a standardisation causing the poor treatment results (Schelin, 2009; Malmberg, 2010a; Rosén, 2009; Pedersen, 2007).

Considering the uniqueness of patients and their varying degrees of BPH symptoms, the standardised treatment created high variation in treatment results. Recovery rates for ProstaLund's TUMT machine were, in the late

[26] Special attention is drawn to organs located near the prostate because of their great importance for a man to be able to perform basic functions, such as urination, sexual activities, etc.

1990s, pushing towards 50%. This number is to be compared with the surgical alternative, TURP, with its 75% recovery rate (Flensburg, 2005; Wagrell, 2005; Bolmsjö, 2005; Pedersen, 2007; Malmberg, 2010a). Consequently, after a few years' use at various hospitals, the method did not turn out to be the perfect alternative to surgery for which enthusiasts had initially hoped. Rather, in some cases, it fulfilled a function as a complementary method to minimally invasive surgery, accomplishing good results for some patients, often in combination with other kinds of treatment. These high expectations and the sudden realisation of TUMT's limitations caused a sudden decline in its use. Instead of becoming a new standard procedure for the treatment of enlarged prostate, TUMT was seen as a potential alternative treatment to standard surgery. And, as a complementary method, TUMT was no longer a low-cost alternative but an additional cost to clinics' budgets. (Pedersen, 2007; Norlén, 2007; Malmberg, 2010a).

In 1995, the short era of TUMT technology came to an end. As a commercial product, it hit rock bottom and, with little scientific evidence to serve as witness to its usefulness or value, TUMT came to an abrupt end after 15 years of development and use in BPH treatment.

4.4.1 A SECOND GENERATION OF MICROWAVE TECHNOLOGY

In 1995, users in Sweden realised TUMT was not what they had expected and the technology was slowly phased out at urology clinics all over the country. ProstaLund sales numbers were low and, as the general tendency continued, other such companies around the world went out of business (Bolmsjö, 2005). ProstaLund had experienced a couple of years of good sales, but Bolmsjö re-evaluated the situation and concluded that TUMT production had come to an end and it was time to move on; it was a seemingly tough decision for the company, considering the years of investment in production equipment, the hiring of new employees and the new relationships with subcontractors and suppliers. The investments were not only physical in character, but also in terms of the years of assimilated knowledge in the development and production of TUMT machines. Bolmsjö was, in spite of all these prior investments, unable to see how the company could manage in an environment where the technology had run its course.

It could have been the end of TUMT treatment and, in some sense, it was, but not fully. Because at this point the story took an interesting turn, with the technology going back into development. The following development is

yet another story with diverse prerequisites on the producer side, creating new implications for its users.

4.4.2 SCEPTICISM IN USE, OPTIMISM IN PRODUCTION

Going back two years in time, to 1993, a convention for Swedish urologists was held in Kalmar, Sweden. Urologists and industry people met for a few days to lecture and to present progress in treatment and research. Bolmsjö was invited to the congress, where he encountered Schelin, who was head of the urology department at Kalmar Regional hospital (Kalmar länssjukhus). The two met for an informal encounter one afternoon, where Bolmsjö made an effort to convince Schelin to initiate TUMT treatment at the urology clinic in Kalmar. However, Schelin refused, due to the poor results he experienced when using microwave technology from another producer. Even if Schelin at that time had used a device other than ProstaLund (a device called Easy P constructed by a urologist at Karolinska Hospital in Stockholm[27]), he argued that all TUMT technologies produced equivalent results. Schelin further explained that, out of thirteen patients, only two had had successful treatment with Easy P (Schelin, 2009; Bolmsjö, 2010). In nine cases, there was no effect at all, while the remaining two patients had severe complications with, among other things, incontinence. Schelin further argued that any 'blind method' like TUMT would never be able to achieve results as good as surgery, due to individual variations in symptoms and physical condition among patients. But, if it were possible to control the exact amount of heat used in each treatment, and somehow measure intra-prostatic temperature to account for individual requirements in treatment, then there might be something to the method. Bolmsjö listened but had no inclination to develop the method further, because, in 1993, business was still good for ProstaLund. Their discussion ended there.

Returning to 1995, when ProstaLund faced the closure of its business, something happened that saved the company from closing down. The salvation for ProstaLund was not solely – as is possible to imagine at first glance – the opportunity to further develop the method, but rather, a governmental agency, NUTEK. NUTEK's committee of technological development offered ProstaLund funding to continue the development of its technology, which could save it from going out of business. With no users in sight, but with the new

[27] This was a machine manufactured in very small scale and almost only used at Karolinska Hospital by its inventor, a urologist named Wiksell.

liquidity, the second round of development could start. Schelin was contacted once more and, on the verge of ruin, a development project was initiated at Kalmar hospital by means of external capital. Whilst the technological development at the firm was financed by NUTEK, the urology department at Kalmar Hospital also applied for grants from the county council in Kalmar. It was granted funding from Kalmar County Council encompassing one training urologist to run the development project part time. (Schelin, 2010; Wagrell, 2007; Bolmsjö, 2006)

4.4.3 THE TECHNOLOGICAL DEVELOPMENT OF THE SECOND GENERATION TUMT

TUMT had many attractive features, but it was the treatment results that needed to be enhanced, results had to be at the same level as the minimally invasive surgical method TURP. The guiding purpose of the project was to find a way to measure the exact intra-prostatic temperature during treatment to create a treatment with individually adjustable results. This temperature information could, in combination with some calculations, generate information about the amount of tissue destroyed in the prostate gland during treatment. The measure of temperature in TUMT treatment involves a high-level of technical complexity, because microwaves create magnetic fields that hamper accurate temperature measurements. When Bolmsjö found a way to accurately measure tissue temperature within a microwave field, the team started to realise it might be onto something (Bolmsjö, 2006, Wagrell, 2007).

The first clinical trials began in 1995 and were undertaken by an ST (specialist-in-training) urologist, and a senior urologist. The guiding purpose of the study was to see whether intra-prostatic temperature was an indicator for treatment length and strength of microwave radiation. Using temperature as the determinant for radiation strength made possible the supervision of treatment, which could now be adjusted to individual needs. The team took the measurement using three sensors that were inserted through the pelvic floor. Each sensor had five measuring points, providing a total of 15 temperature indicators. The sensors supplied the physician with continuous information about intra-prostatic temperatures, indicating fluctuations in temperature during treatment. The treatment procedure was more flexible, with temperature as an indicator of when to intensify or lower the effect of microwaves. The method required spinal anaesthesia, mostly to enable the insertion of the sensors. But, to test their hypothesis, they had to use surgical methods, which

undermined the beneficial features[28] of TUMT. Established in the first trials was the great variation in the correlation between intra-prostatic temperatures and tissue destruction. The team concluded the high variance to be correlated with blood flow, and thus there was a high correlation between blood flow and intra-prostatic temperature (Wagrell, 2007, Bolmsjö, 2006).

Blood circulating through the prostate gland during treatment has a cooling effect – the same effect as antifreeze liquid has on an engine. To fully analyse the actual effect of blood flow and the overall course of events during treatment, Schelin contacted a good friend, Bivner, CEO at B-K Medical, to borrow an ultrasound machine with a colour Doppler. Attaching the ultrasound trans-rectal during treatment, they were able to follow changes in blood flow during treatment. With results from the Doppler, it was settled that blood flow in the prostate grew enormously after 7-8 minutes of treatment, causing a significant cooling effect that reduced the impact of radiation. Results from the temperature study confirmed a recovery rate of 75% – a great improvement from the earlier 50% (Schelin, 2009).

For ProstaLund's account, Bolmsjö spent a lot of time in Kalmar, taking part in the development as he constructed new technical solutions, keeping pace with new findings (Bolmsjö, 2006; Wagrell, 2007; Schelin, 2010). One large challenge concerned how to convert the new findings into technical functions and practical solutions without forfeiting the policlinic aspect of microwave treatment. At the same time, it was pivotal to improve treatment results – *TUMT had to be equally efficient as surgery*. The first clinical trials had been performed as a surgical procedure, resulting in patients being hospitalised after the intervention since it was equivalent to surgery. Another issue was manoeuvring the machine that had become more complex due to its new functions. With more parameters to consider, the treatment had now developed its own methodology to a larger extent than had the first generation TUMT. The technical challenge was primarily to measure the intra-prostatic temperature and blood flow without using surgical intervention. Since microwave radiation of the prostate was accomplished through an anal catheter, a delivery device, the small catheter running through the urethra was the easiest way to reach the prostate gland without surgical intervention, see Figure 4 below. The answer was thus to equip the catheter with a small thermometer, (in the form of a needle) and place it inside of the catheter. The intra-prostatic temperature

[28] The main benefit of TUMT was the policlinic treatment method, with no anesthesia and no hospitalisation needed.

could, through this needle-thermometer device, be measured without surgical intervention (Wagrell, 1999, Schelin, 2006)

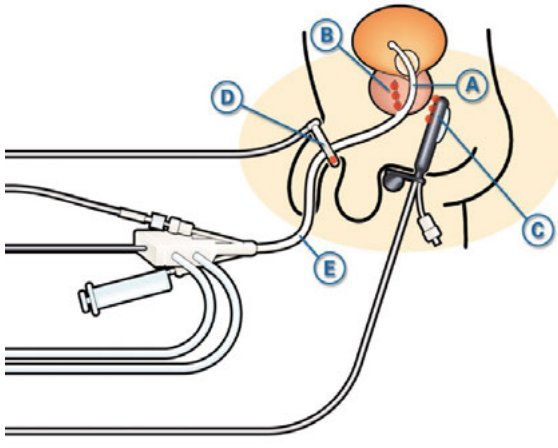

Figure 3. Microwave treatment of BPH

Only seven needle catheters were made to conduct the first trials, because of the extreme costs of producing them. For the first clinical 'needle' study, the catheters were all mechanically constructed in ProstaLund's workshop. Seven patients participated – one for each catheter produced since these catheters were disposable devices. Recovery results were 100% for these first seven patients, which was insufficient to draw any conclusions considering the small size of this sample group, even though it was clear the needle-catheter had served its purpose. To gauge the amount of tissue destroyed in each treatment, the team measured the prostate with ultrasound before and after treatment, thus indicating the approximate quantity of tissue destruction in successful interventions.

The study continued with the new catheter. A total of 100 patients participated in the study and, due to ultrasound measurements, the team concluded that the best results were obtained when tissue destruction was at a level of 30%. However, to judge when a patient had reached a tissue destruction of 30% during treatment was difficult. The only indicator available at the time was temperature, which said little about, for example, the *pace* of tissue destruction. To achieve successful treatments required an experienced urologist able to interpret the somewhat ambiguous data provided during treatment. In order to make the machine commercially viable, it had to become more user-friendly in terms of delivering more concrete and extensive data to facilitate use.

NEW DATA TO CALCULATE TISSUE DESTRUCTION

The solution to the problem of tissue destruction was provided by an equation derived from geology that was initially constructed to calculate heat per mass in oil wells. Bolmsjö came across the algorithm when reading a dissertation discussing treatment of liver cancer, where the algorithm was applied to calculate the dose of temperature in laser radiation. Bolmsjö used the same algorithm but changed one variable, see Figure 6 below. He then used the results from his team's own clinical studies and ran that data backwards through the algorithm. Then, by comparing results provided by the algorithm with their own calculations of 'optimal' tissue destruction, they found the results to be consistent. After more extensive testing, it was established that the algorithm had served its purpose. It was integrated into the microwave machine that now encompassed a computer, which delivered information about the intra-prostatic temperature, blood flow through the prostate, and tissue destruction. This information could help the physician to adjust treatment to the patient's individual needs, and thereby achieve better treatment results. Also, the treatment retained its economic benefits as a policlinic treatment (Bolmsjö, 2005; Wagrell, 2010).

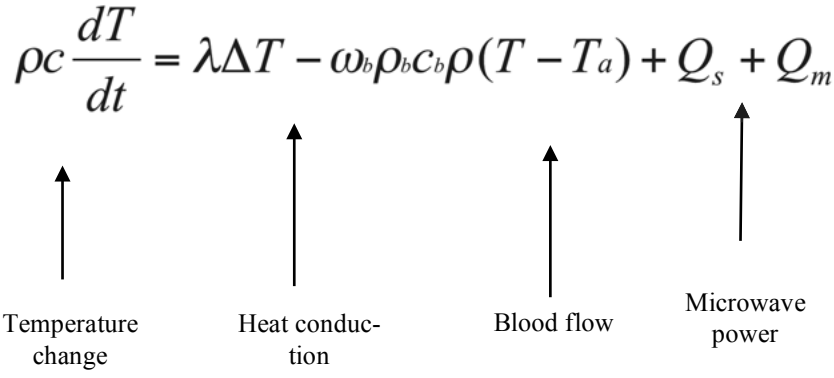

Figure 4. The algorithm used to calculate tissue destruction (Wagrell, 1999)

The new microwave technology was called *PLFT – Prosta Lund Feedback Therapy*. This machine was a further developed TUMT-technology. Treatment time was set between 15 and 70 minutes. The thermometer enabled full control of the temperature during treatment, so the risk of overheating[29] was radically reduced. The development of PLFT had transformed microwave technology in that this new version was more of a method rather than just a technological device as TUMT had been called. The advanced technical features of PLFT made it possible for urologists to perform an individually adjusted treatment. With help from a range of data, urologists could continuously monitor treatment and make the necessary adjustments in radiation strength, etc. This treatment method required higher skills in interpreting data and adjusting the treatment in relation to that data. The new challenge for urologists concerned how to respond to specific changes in data flow (Wagrell, 2005; Bolmsjö, 2005; Schelin, 2010; Carringer, 2007).

THE SCIENTIFIC PRODUCTION OF MICROWAVE TREATMENT

Over a period of five years, the technology had evolved into a method providing an individualised, microwave treatment of BPH. The technology, with the appurtenant devices, had become more advanced and methodological features had been developed alongside the advancement of technical features. However, the specific PLFT-device was not scientifically embedded in the public healthcare user setting. With the first failure of the technology still fresh in the mind of the medical community, microwaves garnered little interest among

[29] Overheating of the prostate during treatment is one of the most common complications in microwave treatment (Pedersen, 2007; Carringer, 2007).

urologists. The development project in Kalmar, consequently, did not attract much attention.

However, it was necessary for the team to scientifically demonstrate the potential of their new findings and a doctoral research project was initiated at the urology clinic of Uppsala University Hospital in 1998. It was the same ST urologist from Kalmar that continued the project at Uppsala University Hospital. Initially, the project met resistance. The urologists from Kalmar had to convince the head of the Uppsala urology department, Norlén, who was finally convinced as the results in the Kalmar-study seemed interesting and pointed towards an enhanced microwave treatment of BPH. (Norlén, 2007; Wagrell, 2010; Häggman, 2007)[30]. The PhD study lasted another two years, observed 35 patients and resulted in a thesis that was defended and accepted in 2000 at Uppsala University (Ibid).

Figure 5. A PLFT -Machine from 1999

[30] The urology department at Uppsala University Hospital had been one of the largest antagonists towards microwave treatment in the early 1990s. At the time, it would not approve a method with such a weak base of evidence. With the new results from the Kalmar study, the head of the clinic in Uppsala decided that the project should continue as a research project, i.e., a PhD project. PhD studies commonly have to be conducted, or at least *defended*, at a university with a medical faculty in order to go through the 'scientific process'.

Generally, between the years 1990 and 2000, TUMT technology went from being a non-scientific method to a scientifically evaluated technology. The large number of published articles in scientific journals was another indicator of the fact that microwaves had become a 'scientific device' by 2000. With regard to the number of articles published on the subject of BPH and TUMT, a review of scientific publications shows that, before 1992, there were no articles published on the subject. The first articles appear during 1992. However, there was a peak in publications in 1999 and 2000, all in medical journals, and the majority in journals within the field of urology. Furthermore, the countries with the highest representation of publications on microwave technology are the US, Italy, Sweden and the Netherlands, which suggests that countries involved in the early adaptation of microwave therapy had a high representation in the following 'scientific era' of microwave treatment around the year 2000. Also, in the large BPH evaluation made by SBU (Swedish agency for health technology assessment and assessment of social services) in 2011, the PLFT method is one of several methods evaluated for therapeutic treatment of BPH. In this evaluation PLFT, is categorised as a method within the category of 'surgical options'. Consequently, microwave technology is still being used, and in the SBU, inquiry is depicted as the most common alternative to invasive surgery in BPH treatment (SBU, 2011). The report further states that TUMT is the further developed version of microwave treatment and that a considerable amount of the technological improvements in the microwave technology were made in Sweden. In 2011, it seems that TUMT is the most common alternative to surgery. With this in mind, we shall now continue to investigate the company ProstaLund. We shall follow the struggle of this company to further develop its business between the years 1995 and 2010, so as to fully comprehend the dilemmas of developing a new technology from the producer's perspective. The next section is focussed on ProstaLund and the industrial context around the company. However, the following sections will scrutinise the using context in more detail. Even if the two contexts of healthcare and ProstaLund are highly intertwined, it is a way to explicitly point to each context's specific characteristics and drivers.

4.5 PROSTALUND 1995-2010

Starting as a small consultancy firm in the 1980s, later developing into a TUMT producer in 1990, and more or less going out of business in 1995 and

then, just about surviving through NUTEK's financial support; after being saved by NUTEK, what happened with ProstaLund and its PLFT technology?

Bolmsjö was mostly occupied with the development project at Kalmar Hospital, constructing technical solutions in pace with the progress being made in clinical trials. Meanwhile, the 'TUMT business' continued as normal, even if a bit slower. There were not many new users at this stage, but the company was kept afloat through the new capital and previous customers. Once again, it was a tough time for ProstaLund. If most of the microwave producers had gone out of business in 1995, then, in 1998, business had gotten even worse, with sales numbers still pointing downwards. In Sweden, 15-20 TUMT devices were sold between 1992 and 1996. Generally speaking, selling microwave technology was not an easy task, and even more difficult was to achieve widespread use. In 1998, the company applied a strategy to achieve "goodwill" among Swedish urologists, whereby they placed devices at larger clinics for free and offered training. Unfortunately, it did not generate any larger long-term results (Bolmsjö, 2005; Rosén, 2008).

Among other producers of microwave technology at that time were a French manufacturer, Brucker, and a U.S.-based company, Urologix (de Wildt & de la Rosette, 2000). These companies produced TUMT machines equal to ProstaLund's TUMT. The latter one was traded on Nasdaq and acquired venture capital of 100 million USD each in 1998 (Rosén, 2009). The general use of microwave technology at the time was rather limited, but at the same time there was an increased interest in the technology from a producer and investor perspective. Compared to the high investments made in similar international companies providing microwave devices, abroad such as Prostatronics and Urologix, ProstaLund stand out as a small company struggling with both development and earning revenue out of its existing production structure. Anyhow, ProstaLund now had a new dilemma: it had a new technological device, a new method for treatment of BPH, but no money left to realise commercial production of their new needle-catheter. (Bolmsjö, 2009; Rosén, 2008)

The main difficulty in the technical development had been to construct the needle-catheter. Other issues related to the assembly of the machine, the programming of computer software, and getting data into a user-friendly format. The years 1995-1998 had been full of clinical testing and technical development. Bolmsjö had put together prototypes of all technical solutions in ProstaLund's workshop, which he successively reconstructed according to changing requirements and developments. These reconstructions were financed with NUTEK money and were never greenlit for any large-scale production (Bolmsjö, 2005; Nilsson, 2005).

In 1998, when the clinical trials ended at Kalmar hospital and PLFT was on its way to becoming scientifically approved at Uppsala University Hospital, the company met its first real production challenge. If the largest hindrance, from a user perspective, had been to overcome standardised treatment, the question from a production perspective was how to achieve mass production at a viable price that allowed proper commercialisation. One thing was to construct one or two devices in the workshop, but to achieve commercial production of the PLFT device and the needle catheter required another kind of knowledge and capacity. The catheter was especially problematic due to its size and function. Hence, accomplishing mass production of the catheter turned out to be a real brainteaser (Bolmsjö, 2005; Nilsson, 2005).

ProstaLund's TUMT machine had used a catheter with an integrated cooling system – water circulated in the catheter to avoid damage and overheating in surrounding tissue and organs. But this new catheter was more advanced, and demands on quality and functions were very high. ProstaLund had earlier used a subcontractor, Medical Rubber (MR), in the production of catheters for the first generation TUMT. MR was experienced in production of rubber solutions for medical use, but also in process production in medical equipment. Soon after initiating a dialogue with MR, Bolmsjö realised that mass production of the catheter would be very expensive. First, to enable large-scale production at a reasonable price, there were high demands on adaptations from both parts, i.e., the construction of the catheter had to adapt to the limitations in the production structure and vice versa. Secondly, producing a technically advanced device such as the needle catheter would require months of expensive adjustments and further development of existing facilities and processes. Once again, it came down to financial means. ProstaLund was low in liquidity after years of scarce income. The solution to this financial distress was resolved by aid from the governmental agency, NUTEK. The agency offered financial support for small-to-mid-sized firms to develop and commercialise their existing technologies. NUTEK evaluated ProstaLund's request for capital to develop a production process for the needle catheter and offered it 1 million SEK through LFTP[31] (*the county council's fund for technology tendering and product development*). But NUTEK's funding was not unconditional; since its policy for fundraising was to ensure commercialisation, the company receiving the grant had to find co-financers as a kind of guarantee of the technology's potential. ProstaLund made a business plan and

[31] LFTP – *Landstingens Fond för TeknikUpphandling och Produktutveckling* – Today NIVO

contacted venture capitalists who might have a possible interest in the business. ProstaLund chose the VC firm, Swedstart, which granted ProstaLund an additional 15 million SEK in venture capital. After a few months of development and trials, ProstaLund and MR succeeded in producing the catheter for half of the initial cost, enabled by MR's extensive knowledge of production process technology and financial support (Bolmsjö, 2005; Nilsson, 2005).

The development of process production had been successful, but the prerequisites for the company had been altered once more during the process. With venture capitalists now in the company, the conditions had changed. Three main goals were immediately outlined by the new owners: the first was to appoint a new CEO. The second was to build a new and larger organisation, which was to prepare for the third goal of entering the US market. In 1998, a new 'professional' CEO, Rulf, was appointed by the new owners. A large restructuring of the organisation started. New personnel were hired, mostly in marketing and sales with the purpose of increasing sales and entrenching a continuous use of the product among already existing customers. After the entrance of VC, ProstaLund expanded its business to encompass 40 employees within a year (Bolmsjö, 2005; Pancarz, 2005).

Production went through reorganisation as well. Among other things, production of hardware was outsourced to PartnerTech[32]. With PartnerTech taking care of the assembly of the machine, new producers entered the picture, which is why certain components were added that changed some features of the machine. Other components were specially designed for the PLFT machine and were critical to its function, which resulted in new suppliers for PartnerTech that had to include some of ProstaLund's established contractors into its supplier network (Bolmsjö, 2009; Nilsson, 2005; Flensburg, 2005).

Production operated on a forecast of six months of estimated sales, not production to order. Some of the production still took place on ProstaLund's premises, but this concerned customisation of the hardware to suit specific contextual circumstances in each user-setting, such as language, antennas, heat devices, and electricity plugs (Nilsson, 2005; Bolmsjö, 2005; Pancarz, 2005).

Concerning the new third goal of the company, to enter the US market, there were some structural impediments to legal approval to market and sell

[32] PartnerTech is a big producer of technical solutions, which is located in Sweden. It has many med-tech companies as customers (as evidenced by a series of case studies on several life-science companies conducted at Uppsala STS center in 2001-05).

the method in the U.S. Permits are handled by the FDA[33] (Food and Drug Administration) and, when the company was restructuring and about to start up commercial production in 1998, it had to engage the FDA as a development partner to facilitate the permit procedure. Involving the FDA at an early stage meant adjustments to the device and its production to U.S. standards (Pancarz, 2006; Bolmsjö, 2005; Flensburg, 2005; Nilsson, 2005).

The U.S. market was considered as important, not only in terms of it being a large market, but because it was held to be a gateway to other markets as well. Consequently, preparing for entry into the U.S. market, ProstaLund adjusted its data from clinical trials to FDA standards. The changes did not only encompass technical adjustments in the device, but the administrative structure within the company had to undergo large adaptations that had a large impact on the administration of the company (Pancarz, 2005). For every step of the changes – technical, methodological or administrative – the FDA sent inspectors to Sweden to ensure that the adjustments followed its rules and standards. ProstaLund did experience some difficulties in making the adjustments; employees claimed that being tied to an organisation like the FDA, with its constant changes in rules, gave the company a large amount of extra administrative work, continuously revising all of its documentation (Pancarz, 2005; Flensburg, 2005). It was further claimed to bring rigidity into the organisation and hamper work under many circumstances, from education of users to paperwork. The FDA also influenced the choice of supplier when production was outsourced in 1998. When ProstaLund first chose to outsource production to PartnerTech, they had selected eight suitable suppliers in Europe before making their final decision. PartnerTech got the contract not only because of its high standards of production, which other suppliers had as well. The decisive factor was rather related to its technical certification in a system known as QSR. QSR certification is a necessity in getting a marketing permit in the United States. In Europe, there is a corresponding regulation in the CE Marking, for which ProstaLund was approved in 1999. (Pancarz, 2005; Bolmsjö, 2005; Flensburg, 2005; Nilsson, 2005) Within this larger organisation, greater efforts were put into production processes, administration and marketing. So, what happened with sales during this period? Further, did the company really generate any profit?

Between 1998 and 2000, sales were still at a low level and few urologists seemed willing to learn and practice the further developed method. ProstaLund did not generate enough money to be self-sufficient and to keep it from

[33] The FDA is a United States authority, granting permits for sales of medical technology, among other things.

bankruptcy, more venture capital was acquired and the owner structure was again changed. New capital arrived just as the company ran out of financial means. The larger investors were SEB, Capman, Gustav Douglas, Latour, STENA and Engströmsgruppen, which together invested about 300 million SEK in ProstaLund. Even if liquidity kept coming in, sales continued to decline. ProstaLund had to cut down on costs. In 2000, it was forced to dismiss employees, with further declines in sales and turnover forcing CEO Rulf to leave the company in 2001 and the founder, Bolmsjö, resuming his post as CEO. (Bolmsjö, 2005; Pancarz, 2005; Flensburg, 2005)

Between the years 2000 and 2004, sales increased somewhat but were still relatively scarce. Even more problematic than sales were motivating users into continuous and active use. In 2005, ProstaLund had 25 machines in Swedish hospitals, but few were in active use. Still striving to increase sales, in 2004, prospects suddenly got a little bit better, sales slowly increased and ProstaLund founded a subsidiary in Germany. The relationship with its US distributor deepened as ProstaLund sent over personnel to support the distributor and to educate American users. The German and American markets were considered the most important in 2004, but machines were sold all over the world, for example, in China, Korea, and Chile. Germany was the only country with a subsidiary; in all other countries, ProstaLund used local distributors. (Bolmsjö, 2005; Rosén, 2009)

In 2006, sales were still low and the number of employees was down to 12. The usage of sold machines increased a little, but getting new sales was still a difficult task. This long period with a lack of positive cash flow and no revenue made some of the larger owners leave the company. Douglas and Latour left, while SEB and Capman made a final investment on the condition of a total restructuring of the company. Undergoing its second restructuring, the company hired another new 'professional' CEO, Rosén in July 2006. The restructuring ended in a total redirection of strategy. All employees were dismissed and the company moved its premises and headquarters from Lund to Uppsala. Some of the earlier collaborations with suppliers were ended, though PartnerTech continued to manage the assembly of the hardware. A new supplier was brought in to handle software development, customisation and product-care. A Lund-based consultancy firm, Epsilon, specialised in technology and system development, and hired some of the former employees at ProstaLund and, in return, ProstaLund committed itself to long-term collaboration and development (Rosén, 2008, 2009). The new CEO made radical changes to the company, with the final objective of achieving positive cash flow as soon as possible. The company had left the German market and closed down

the subsidiary. Instead, all focus and energy was redirected once again towards the U.S. market, which had been a condition of the owners, SEB and Capman (Rosén, 2008).

With the U.S. users finally in sight, the new team at ProstaLund managed to turn the company around and increase sales by 55% during the first six months of 2007, mainly through attracting new users in the U.S. market. Without any obvious explanation, in August of the same year, sales went down to zero overnight. After some time, it turned out that all producers of minimally invasive methods had experienced a decline in use (Malaeb, Yu, McBean & Elliot, 2012). The downfall was a combination of many unfortunate circumstances. First, insurance companies started to withdraw their support for minimally invasive methods in the treatment of BPH, owing to the fact that many of the microwave devices available in the U.S. were still the first generation of TUMT technologies, therefore less efficient. Of course, the TUMT devices available in the U.S. in 2008 were more advanced in comparison to the very first TUMT devices provided in the 1990s. Yet, the aggregated long-term TUMT data, which included all manufacturers and devices in use in the U.S., showed that the treatment could not provide sustainable, long-term results in the treatment of BPH. Only temporary improvements in the condition could be proved and the effects of TUMT treatment on the condition BPH was - from the agencies' perspective - equal to medication with drugs, such as alpha-blockers. The new long-term data showed that patients treated with TUMT in the U.S. were, sooner or later, in need of surgery anyway. Consequently, the perception of TUMT treatment, which in the eyes of the insurance companies, had become a redundant expenditure and reimbursement[34] was lowered. In 2008, reimbursement for minimally invasive methods like TUMT and also PLFT was set at a level just below 3,000 USD per treatment, whereas in 2006 reimbursement had been right above 4,000 USD, a decrease of 1,000 USD in two years (Stovsky & Jaeger, 2008). The lower reimbursement rate made TUMT treatments more expensive for U.S. healthcare providers and as a consequence use of TUMT in general declined in the U.S. during 2008[35] (Malaeb

[34] In the United States, reimbursement for new technology in medical treatment is geared to encourage new high-tech solutions. Initially, reimbursements paid by insurance companies are always rather high for new methods; after time passes, reimbursement is normally lowered.

[35] Healthcare in the U.S. is commonly revenue driven, which is why reimbursement levels and insurance companies' attitudes towards new methods are very important.

et al., 2012). As the agencies had not made any distinction between the different manufacturers' devices in their evaluation, the decline in sales affected ProstaLund as well, even if their machines did provide better results than surgery according to the Swedish clinical studies.

The company now faced one of its biggest challenges so far: reassuring the U.S. system of insurance companies and CMS[36] of the potential of PLFT, so as to achieve a fair reimbursement level for its method. ProstaLund had to approach the insurance companies directly and argue its case: that their specific PLFT device, with its further developed method, indeed created long-term and sustainable results (Rosén, 2008, 2009; Wagrell, 2010).

Even if American users were the main focus, Swedish users were still important. A lot of effort was made to re-educate urologists in the use of PLFT. The largest impediment for the company to overcome in Sweden in 2008 was to make physicians try out PLFT, to give it chance before dismissing it. The company strived to understand the triggers a Swedish urologist needed in order to change their treatment behaviour. ProstaLund's strategic plan in 2008, for the Swedish users, was to await the predicted demographic changes that, according to ProstaLund calculations, would occur in 2010. The strategy was based on the illness rates of 2008 and future demographic changes, where there would be an approximate increase of 27,000 patients in need of treatment for BPH up to 2010. According to ProstaLund's calculations, about 85% of all invasive treatments in Sweden were performed with TURP (invasive surgery). Since there had been no increase in capacity in the healthcare system in 2008 to handle this imminent demographic increase, ProstaLund put its faith in a second chance for PLFT (Rosén, 2009).

In 2010, the company had undergone further organisational restructuring; the former owners SEB and Capman withdrew their ownership the same year. It was one of the darkest moments for the company thus far, and the closure of the business seemed near. If it had not been for the CEO's great confidence in the method and willingness to reach out, the company would not have survived. Rosén found new venture capital and, in 2010, ProstaLund had new owners again. The largest owner was Bo Håkansson with 35%, the next 35% was divided between three owners, Rosén himself, F. Lindgren and Kockum.

[36] Centres for Medicare & Medicaid Services, a governmental institution deciding on reimbursement levels

Other large owners were Miab and Inventor Invest, and then there were another 200 small owners like employees in the company, etc. The company thus survived the financial crisis of 2009 (Rosén, 2009).

Customers were, in 2010, equally divided between the U.S. and Sweden, with the number of active users in Sweden being about 20. All users had individual agreements with ProstaLund and the cost of a machine was about 6 million SEK. For leasing customers, each treatment amounted to about 10,000 SEK in 'hardware', representing the facility cost for renting and for the products used in each treatment, such as the needle catheter and use of the device (Rosén, 2009). The strategy was to acquire new users in Sweden by offering economic benefits and 'patient-friendliness'. If the company had tried to convince urologists to try out its method in 2008, the focus had changed in 2010. Partly due to new regulations, such as leasing contracts had become more difficult to establish around 2009-2010, because of new procurement regulations. As ProstaLund was a small company they found procurement procedures to be complicated and expensive. To rely solely on procurement procedures and public purchasers was an insecure 'strategy'. The new target group was divisional executives at public hospitals and to some degree even politicians, who were thought to have the economic power to change treatment recommendations and the organisational climate in favour of PLFT (Rosén, 2009).

ProstaLund's customers, urologists in public healthcare, operate in a context where they are influenced first by national/regional policy and regulations driven by the NPM reform presented in Section 4.2 and secondly by the specific preconditions at the local hospital and department. The following two chapters, 5 & 6, will focus on the users of the ProstaLund microwave technology and the Swedish public healthcare context. The healthcare sector has thus far figured as a developing context. However, when the perspectives now change, from development to concerning commercial use of the technology in public healthcare settings, other preconditions for embedding the technology applies. Chapter 5 briefly describes the organisation of the Swedish healthcare system on a national level as well as the most salient regulations that will affect the embedding of ProstaLund's TUMT device into use. Chapter 6 describes four specific use contexts, hospitals, that have interacted with ProstaLund and used the TUMT device.

5. USERS OF TUMT - THE SWEDISH PUBLIC HEALTHCARE CONTEXT

In order for ProstaLund to achieve *widespread* use of their device, it is decisive that their microwave technology becomes embedded at a systemic level. Moreover, the technology needs to develop an interface towards existing regulations, purchasing and procurement procedures. Finally, the method also needs to relate to clinical praxis, namely the behaviour of physicians.
The *first section* of this chapter describes how public healthcare is organised on a national level. The *second section* describes how the use and introduction of medical technologies are regulated by central agencies and what kind of knowledge they base their assessments on[37]. The *third section* describes a typical public purchasing and procurement procedure of medical technology, with a special note on innovation procurement. The *fourth section* describes hospital reimbursement of medical technology and the *fifth section* discusses some general clinical praxis issues, concerning the education of urologists and how this influences the possibilities for ProstaLund's new method to become embedded into the system.

5.1 A COUNTY-BASED DECENTRALISED SETTING

This section gives a brief introduction to the overall organisation of Swedish healthcare. The organisation of healthcare is significant to the embedding of ProstaLund's device because it entails contextual differences and settles the frames for how healthcare services and thus the use of certain methods and devices can be provided within the system. The Swedish healthcare system is regionally decentralised and therefore to a large extent locally controlled by the self-governing counties. At a state level, the central control tools, above

[37] It is worth noting that this case study stretches from the early 1990s - when the NPM regulations were in their infancy - until around 2010. Over these two decades, the regulations have been further developed, perhaps some of the descriptions of the organisation made here are not representative with regard to some of the most current models applied. However, the description of the regulations is significant in relation to the embedding of microwave technology over time in the context of Swedish healthcare

legislation, includes such as knowledge management tools, performance-based compensation or targeted initiatives for specific areas[38].

Sweden has 20 counties and four regions[39] (SKL, 2013), which are all self-governed units responsible for providing health services. The idea behind the reform leading to decentralisation was first to create higher efficiency in the system in general (Anell, 1990), but also to attend to the counties' individual interests and capabilities to enact an efficient system. There are significant differences between the counties. Some counties only provide basic services due to a small taxpaying population and are thus constrained to buy healthcare services from other larger counties. Whereas others sell their highly-specialised healthcare services. However, this kind of coordination of services between counties are organised according to a selling-buying logic.

A pressing issue for the counties has concerned how to best coordinate the relationship between provider and buyer. In the early 1990s, there were several different models in the system to coordinate payments and services. The most frequent model initially was the '*purchaser provider'* model that later was abandoned in favour of the '*customer choice'* model (SOU, 2002:31). In the customer choice model, the patients (citizens) are free to choose from a range of suppliers, private or public. Since January 2015, patients are free to choose providers in open specialised care and primary care without referral, even outside their own county borders (prop. 2013/14:106). The idea behind this model is that if the money follows the patient, it will enhance the competitive aspect among care providers and hospitals that, by providing good healthcare services, attracts patients who are free to choose (Serdén & Heurgren, 2011, p. 340).

Nevertheless, healthcare services are mainly tax-financed through county taxes and approximately 9% of the counties' total revenues are central grants from the government. Incomes from patients' fees are low, amounting to about 2.5% of counties' total revenue (Serdén & Heurgren, 2011). This is a pivotal issue; since virtually all healthcare is tax-financed, all providers, private and public, are dependent on money from the same source, a source which will be fixed and predetermined by tax-income. Due to the rather low degree

[38] Examples of knowledge management tools are national treatment guidelines, performance-based compensation has since 2006 become more common, it includes retroactive reimbursement to counties and regions for fulfilling specific goals in targeted areas, such as mental illness.
[39] Regions have an extended responsibility for development of the region as whole (www.skl.se, 2013). For simplicity, the following text will utilize the term *counties*. In 2017 Sweden has 20 counties, out of which eight have regional, extended, responsibilities (SKL, 2017).

of privatisation, decentralisation is therefore a central feature that makes possible the model-based ideas of the "market", pushing key concepts such as *competition* and *selling and buying* of health services.

To conclude, the counties are self-governed and how they have chosen to organise their healthcare activities and what kinds of healthcare services are provided within each county differs. The organisational and financial prerequisites of the county have a large impact on what kinds of methods and treatments will be brought into use and which devices will be introduced in the specific county's healthcare organisation.

5.2 REGULATING INTRODUCTION OF NEW MEDICAL DEVICES ON A SYSTEMIC LEVEL – EVIDENCE AND HEALTH ECONOMIC ASSESSMENTS

Up until recent years, the counties have been rather free to choose for themselves what kinds of devices (not manufacturers, but type of technology/method) to use in their organisations. But as the number of new technologies/methods in the system have increased and is continuously growing (SKL, 2014) there has been a quest for central evaluations and health economic assessments as to support the counties in their decisions to introduce a specific device (TLV, 2013). The counties have been 'accused' of introducing new devices without sufficient knowledge about their economic effects in practice (SKL, 2014).

Introduction of new medical devices has traditionally been a rather indirect and locally governed process in the Swedish system, without a highly formalised 'introduction' at a systemic level (Vårdanlays, 2015:2), something which is slowly about to change. The common way, of gaining acceptance (outside overarching regulations such as CE- marking) has been a gradual process where new methods slowly have diffused into the system as the direct users themselves have introduced new methods at their hospital departments and clinics.

However, in recent years, the involved agencies[40] and other central actors[41] are gaining more control in the introduction process of new medical technologies. As a consequence, med-tech devices are successively being included in the same kinds of evaluations that previously have been restricted to pharmaceuticals, that is larger health economic assessments. The main objective of policy makers was to coordinate both introduction and procurement of medical technologies on a national level (SKL, 2014).

These assessments, undertaken by central agencies, are based on specific scientifically verified data that achieves a status of being 'objectively true'. These evaluations are based on the idea of Evidence-Based Medicine (EBM), a practice which has entrenched public healthcare with an unparalleled impetus and played a central role in enabling the growth and establishment of important management tools, such as 'national guidelines' (Timmermans & Mauk, 2004; Timmermans et al., 2009, Berg, 1997). The next section shall discuss EBM in short terms so as to pinpoint its role in regulating the introduction and assessments of medical technologies and the methods that come with it.

5.2.1 EVIDENCE-BASED MEDICINE

EBM has been described as the use of the best-available evidence in current treatment in combination with the clinical experience of physicians (Sackett et al., 1996). However, as EBM has developed into a new discipline within

[40] NT-rådet (fd. NLS) Issues recommendations for new therapies, TLV, The Dental and Pharmaceutical Benefits Agency, is a central government agency whose remit is to determine whether a pharmaceutical product, medical device or dental care procedure shall be subsidized by the state (TLV, 2016). SBU, SocialStyrelsen, *National Board of Health and Welfare*, SKL, Swedish Association of Local Authorities and Regions (SALAR)

[41] *TLV* is the most recent agency involved in the regulation of medical technologies. Traditionally, this agency has made health economic assessments of pharmaceuticals and made decisions on which drugs to include in the subvention programme[41]. TLV also base their assessments on traditional health economics models. Medical technologies were added to TLV's activities in 2014 (SKL, 2014, TLV, 2016) and these activities do not yet (in 2016) have a settled structure and still cover only a few products every year. The idea behind TLV's new commission is - among several things - to create organised introduction of new medical technologies on a national level - utilising health economic assessments as the main systematic evaluation of which kinds of medical technologies to bring into the system (SKL 2014, TLV, 2014). The two main arguments for creating a more encompassing controlled introduction of medical technologies on a national level is firstly to better coordinate expensive devices/complex methods on a national level. The second pivotal argument is that the counties lack sufficient *knowledge* to make rational decisions at a local level. The counties allegedly need knowledge in terms of *health economics assessments* in order to make better decisions in their introduction process for medical technology devices (as of 2014; SKL, 2014; TLV, 2014).

healthcare, with time it has gained more importance as a management tool (Bejerot & Hasselbladh, 2008 pp. 11-113; Fredriksson, Blomqvist & Winbladh, 2014).

In many ways, EBM broke with the general trend in healthcare, namely the increased interest in managerial tools derived from private business settings that accompanied the NPM reform described in Chapter 4. Instead of being a managerial tool with focus on financial aspects of healthcare services, it was a tool that derived from within the medical profession itself (Timmermans & Berg, 2003; Hult, 2006). Originally, EBM was not a wholly new phenomenon when it was introduced in the early 1990s. With its philosophical origins in mid-19th century Paris (Sackett et al., 1996), the concept might have been considered 'old news'. However, the interest in EBM increased and successively gained a new meaning for the practice of physicians in the 1990s. Whereas the managerial and financial doctrine of NPM used external forces to 'discipline' the healthcare sector, EBM instead originates from *within* the medical profession itself. It was, primarily, a tool called for by the profession as a discipline to guide the profession and reinforce scientifically reviewed methods as best practice (Hult, 2006)

The real deployment of this tool in medical practice, and the further developments that followed, started around 1992 in Sweden. Initially, the tool was spread within the profession through medical journals. In the early stages of the debate, EBM was criticised but, as it became gradually more accepted, the debate changed direction from concerning the EBM doctrine per se, towards more practical discussions focusing on the *application* of EBM within different medical disciplines (Hult, 2006).

In what ways does EBM coincide with the NPM doctrine, given their diverse origins? I will start to answer this question with a quotation from an article written by professors of medicine, likewise developers and advocates of the EBM doctrine:

"Some fear that evidence-based medicine will be hijacked by purchasers and managers to cut the costs of healthcare. This would not only be a misuse of evidence-based medicine, but suggests a fundamental misunderstanding of its financial consequences. Doctors practising evidence-based medicine will identify and apply the most efficacious interventions to maximise the quality and quantity of life for individual patients; this may raise rather than lower the cost of their care". (Sackett, et. al, 1996, p.72)

This quotation points to the matter of what evidence *is*, how it is *perceived* and how it can be *applied*. Physicians themselves uses EBM as a support in creating the best possible care for their patients. However, as a management tool, the scientific results are assumed to be *evidence* that in turn are *objective facts* that can independently be applied by any physician in any context to any given patient with a specific diagnosis. Evidence-based treatment is supposed to create the same effect independent of context. It also asserts that the costs are to be understood in a larger systemic context, not as isolated events in a specific treatment-context, so that one evidence-based treatment method will create the same costs in any context where it is applied. Such underlying assumptions suit the NPM doctrine fairly well, in that they create a certain standardisation in an otherwise quite scattered range of treatment options. Without imposing any managerial or financial tools into the practice of medicine, EBM functions as a scientific standardisation of practice, which is available not only to physicians but to managers as well. It is a kind of standardisation that is hard to question or contest, since it is comprised of presumably 'objective' scientific facts (Bejeroth & Hasselbladh, 2008).

A second aspect of the quotation is that, yes, as a matter of fact EBM *did* get "hijacked" (to use the same hyperbole as the authors cited above). Managers of healthcare saw the opportunity at hand to use EBM as a tool to monitor healthcare and reduce its costs. How is this possible, in a context where, according to the above quotation, EBM should be the ground for helping doctors choose the best treatment for their patients?

In fact, managers can never force physicians to use a certain method. However, managers can create hospital care policies, such as "to only use evidence-based methods". In such a way, methods that are not considered as evidence-based are excluded and, therefore, EBM has a high impact on what methods are in use at a hospital. In this manner, EBM supports a development direction that constantly moves towards higher standardisation of practice. However, maybe the most important aspect of EBM is that it started as a support system for physicians in clinical decision making and is today foremost utilised to create national guidelines: a tool that is foremost a managerial tool and not a tool for practice (Fredriksson et al., 2014). The scientific base of the tool, as well as the fact that it derives from within the profession, makes it less contestable for physicians. For the single physician to claim a non-evidence-based method above an EBM method for single-patient cases is thus certainly difficult.

In the social sciences, the spread of the phenomenon of EBM in healthcare organisations has been studied, but this is something that has only begun quite recently (Mykhalvoski & Weir, 2004). It has been studied in terms of being a practice transfer and also its power differentials (Raman & Bharadwaj, 2012; Pope, 2003) and as a "travel of ideas" relating to the widespread use of EBM in the healthcare system (Hult, 2006). The role of EBM in the effort towards higher standardisation of healthcare has also been scrutinised (Timmermans et al., 2004), to mention but a few of the approaches studied. However, in general, EBM is considered to be one of the most influential factors in reshaping the practice of medicine, which is underlined by its current position in the education of physicians (Sinclair, 2004) and in medical practice. The main difference in how EBM is investigated by the different disciplines of the social and natural sciences is that the medical disciplines tend to pay attention to the *practical applications* of EBM. The social sciences do not, to the same extent, treat EBM as something decontextualised, but rather, investigate the spread of EBM and how successful the adaptation of EBM depends on both larger social structures and individuals' self-interest or capacity to use evidence-based treatments in practice (Timmermans et al., 2004; Berg, 1997). Consequently, it is recognised that the implementation of rules such as EBM is dependent on contextual factors such as power differentials between professions, medical education and agencies' adoption of EBM. Moreover, EBM in contemporary healthcare is not only practised by physicians themselves, but is implemented as treatment directions from governmental agencies and/or hospital managers through guidelines.

Even though more emphasis is put on scientific evidence in the methods used in healthcare provision today, long-term results are often needed to convince practising professionals, nurses and physicians to accept new methods and change their current treatment patterns. When discussing evidence-based methods, it is easy to assume that all methods used at a hospital would be evidence-based, i.e., scientifically documented. However, the reality is more complex and physicians are faced with complicated decisions in their everyday treatment where they constantly have to re-evaluate specific patient cases that do not apply to the average (Berg, 1997). Even if healthcare personnel strive to use only EBM, there are limitations (Casper & Berg, 1995). In a decentralised system like the Swedish one, it is also a question of how far each hospital is willing to push its quest for EBM, to understand where it is feasible for treatments to be evidence-based or not. One example of such problems is the comment from a division manager at a Swedish hospital, who believed the

boundaries for evidence-based methods often caused delays in the treatment of patients in direct need. Stating that:

"We have patients in intensive care that are not able to verbally respond to the effects of treatment since they are unconscious and it is difficult to see the results by running tests. It is also difficult to conduct clinical trials in intensive care due to the state of the patients under treatment. It is controversial whether or not some of the treatments in use can be considered as evidence-based, which leads to discussions and the exclusion of treatments that do not pass as evidence-based. Such methods have often been in use over longer time periods but lack satisfactory documentation. I think the requirements for evidence sometimes lead to denial of medication that patients could have benefited from". (Division manager at a Swedish hospital)

How EBM is used and interpreted varies among hospitals with regard to which methods are adopted and which are not. The Swedish EBM-debate was fuelled by *Läkartidningen* (the foremost Swedish journal for practising physicians) which, between the years 1996-2002, was among the top ten international medical journals publishing the most articles on the issue of EBM. Many of the authors of these articles were employees of the governmental agency, SBU (Hult, 2006). Even the editor of the article series on EBM had a connection to SBU as an expert advisor on its scientific council (Hult, 2006). Thus, the agencies issuing guidelines, controlling and creating the regulations for healthcare, have played a central role in establishing EBM in the Swedish healthcare system where today it is, first and foremost, utilised as a management tool (Fredriksson, 2012). The next section introduces the central agencies and their roles in regulating the use and introduction of medical technologies into the healthcare system.

5.2.2 REGULATING THE INTRODUCTION AND USE OF MEDICAL DEVICES

The three largest actors controlling and evaluating the use and introduction of medical technologies are the Swedish agency for health technology assessments, (SBU), The Medical Products Agency and the National Board of Health and Welfare (Socialstyrelsen).

The National Board of Health and Welfare is the regulating agency with an encompassing commission to evaluate, inspect and regulate healthcare. This

agency issues general regulations for use of technologies in healthcare that are not product-specific (Socialstyrelsen, 2016). They also issue *national guidelines*, which is one of the most powerful knowledge management tools in the Swedish system (Vårdanalys, 2015:7). Guidelines are, first and foremost, used as a primary source of support by healthcare managers, and they are also, to varying degrees, used as a base in the counties' local treatment programmes. The guidelines grade interventions on a scale of 1-10, weighing treatment outcome against its cost, 1 equals an intervention with good treatment outcome for the patient and a low cost, thus providing high socioeconomic efficiency. Reconnecting to the technology in focus in this thesis, there are yet no guidelines available on BPH treatment, only on prostate cancer (Socialstyrelsen, 2014).

The Medical Products Agency controls suppliers of medical devices and foresees that general prescriptions are followed by the suppliers. They also control planned clinical trials and follow up on reported incidents on medical equipment (Läkemedelsverket, 2016). However, in 1996, the agency published treatment guidelines for BPH as the result of an expert seminar on the subject where TUMT was mentioned as one out of a few viable minimally invasive treatment options (Läkemedelsverket, 2014).

SBU is the agency that traditionally have conducted investigations and written encompassing reports for specific treatment areas, BPH being one of them. SBU is also closely interlinked with the practice of EBM in Sweden constituting, as it does, the foundation for EBM-related decisions in practice (Hult, 2006). SBU undertakes larger inquiries into common diseases, assessing the available treatments for each specific disease. When SBU assesses *new* treatment methods, such as a medical technology, they do so from medical, economic, ethical and social perspectives. Such reports concerning common diseases are normally undertaken every fifth year (SBU, 2017). A new method/technology, like TUMT, cannot be subject to assessment if it has not been in continuous use among a critical group of users over a period of time. This is because scientific data on medical technologies/methods are created in practice, that is, in use at hospitals or healthcare centres, and it is impossible to make an assessment of a specific method without sufficient data.

These SBU reports sometimes serve as a platform for *strategic decisions* in treatment, therefore they have a significant impact on *policy* decisions as well as *management* decisions, especially in larger treatment campaigns for

common diseases. SBU's reports are also used as support when new treatments are considered in the education programmes of training physicians (Carringer, 2007; Rastad, 2010). SBU's evaluations consider a range of aspects, such as financial aspects, safety, long-term results, and statistics for large patient groups, to mention but a few. These evaluations thus provide knowledge that is difficult for physicians to obtain and thus become a way for physicians to keep within given recommendations, guidelines and regulations that are often imposed at management and policy levels.

In 2011 SBU published a report to map the current treatment options available in the treatment of BPH (SBU, 2011). Microwave treatment was reviewed as one out of 15 different surgical methods identified as 'in use' in the system, but it would take until 2011 before TUMT was considered by a central agency. The aim with SBU's reports is to establish praxis for treatment and compare the efficiency of available treatment options as the diverging treatment methods in the Swedish system were claimed to result in a wide variety of praxis. Also, the distribution of responsibility for BPH patients between policlinic providers and urology specialists varies between counties, due to differences in local resources and the traditions in each county (SBU, 2011). However, considering the lack of coherence in praxis, it is difficult to argue that microwave technology is a *widespread* standard procedure.

SBU also grade the scientific value of the methods they assess – a scale ranging from zero to five – where TURP (the surgical method) got the highest score and TUMT was evaluated as a medium-level. At the same time, the same report evaluated TUMT as an established method and as *the most utilised alternative to surgery* (SBU, 2011).

There are several agencies in the system and their work, to some degree, overlaps, yet it is crucial for any new method/technology to be related to the agencies' health economic assessments system. The evaluations are supposed to function as a necessary source of support for the counties when introducing new technologies. This implies that any suppliers of medical technologies, like ProstaLund, have to adapt clinical trials and testing and development of their devices to parameters valued in health economic assessments as the importance of health economic evaluations is increasingly emphasised in the system. Even though ProstaLund's TUMT device mainly operated at a time when these kinds of evaluations were not yet as articulated, the same view on managing healthcare was present even back then, stressing the increased importance of measuring healthcare performance with economic instruments and

EBM practice (Levay & Waks, 2006). This development towards a highly-formalised evaluation elicits a substantially standardised interface between healthcare and the suppliers of medical devices.

However, the introduction and embedding of new technologies into the system has traditionally been an informal process, entailing some early and late adopters of new technologies. When the method is 'accepted' or evaluated, the next step is a public purchase process which includes procurement. This is, so far, a local procedure, at the hospital or county level, with regard to the purchase of medical technologies, hence it is not centrally coordinated.

5.3 PUBLIC PURCHASE AND PROCUREMENT – A LOCAL PROCESS

All new devices have to go through a purchasing process, which includes public procurement. Described here below is a generic purchasing process as it commonly occurs for medical technology within the Swedish healthcare system, that is *at a local level* – within a local county and hospital. The discussion above, concerning health economic assessment of *new* medical technologies at a national level should be looked upon as a 'pre-process' which sets the frames for the local purchase.

In most counties, the purchasing function is centralised, it means that it is a function covering all purchasing activities within the county, not only healthcare supply. However, it is common to have purchase alliances over county borders, with regard to healthcare supply, in order to maximise scale economy (Södergren, 2005). The process of purchasing has the same general design in all counties in Sweden, since it has to keep within the boundaries of legislation, both domestic and EU. Outside the boundaries of the regulatory system, the organisation of purchase departments can differ between counties due to their autonomy.

A purchase process commonly starts from within the organisation: healthcare personnel decides upon necessary investments in new equipment. These decisions are normally joint decisions made by the personnel at the hospital department afterward via discussions and priorities. All kinds of social and material preferences about the devices brought into use are fundamental to the personnel at the department since they affect their everyday work. For

example, a device from one manufacturer can be compatible with the IT system in county A, whereas the same device is not compatible with the IT system in county B. There are always larger or smaller contextual prerequisites closely related to previous investments and established knowledge to be considered in the purchase of new medical devices. Therefore, the purchasing function at a hospital needs to have either close collaboration with the direct users and an all-encompassing knowledge ranging from medical functions and technological standards to organisation-specific issues (Berndes, 2005).

An example is the reorganisation of the purchasing function at Uppsala Akademiska Hospital: The purchasing department in Uppsala County changed its organisational structure in 2001 (Södergren, 2005, 2006; Berndes, 2005). This large University hospital initially had its own purchasing department, governed by the hospital management. At a larger reorganisation at the hospital, undertaken in 2001, the purchasing function was no longer under the control of the hospital, but became a central function serving the whole county - including all kinds of activities such as culture - thus under the government of the county council. When purchasing made part of the hospital, its work was characterised by close collaboration with all of the hospital's different departments. Each medical department was a contractor of internal services provided by the purchasing function. However, the head of the purchasing department, Södergren, stated that their department came to symbolise parsimony at the hospital. The constant demand to cut back on expenditures and increasing resource restraints gave the purchasing department a difficult position when it was part of the hospital's organisation (Södergren, 2005; Berndes, 2005). The hospital, however, was not content with the change and felt it had lost control of a crucial function, which diminished its possibilities of influencing goods provided to its organisation (Ibid). But from the purchasing department's point of view, it was perceived as a positive change since they felt it was easier to follow through with their work, given their now more neutral position. The discontent of the hospital necessitated a compromise where the purchasing department became located within the hospital area in order to facilitate communication (Söderberg, 2005, 2006; Berndes, 2005).

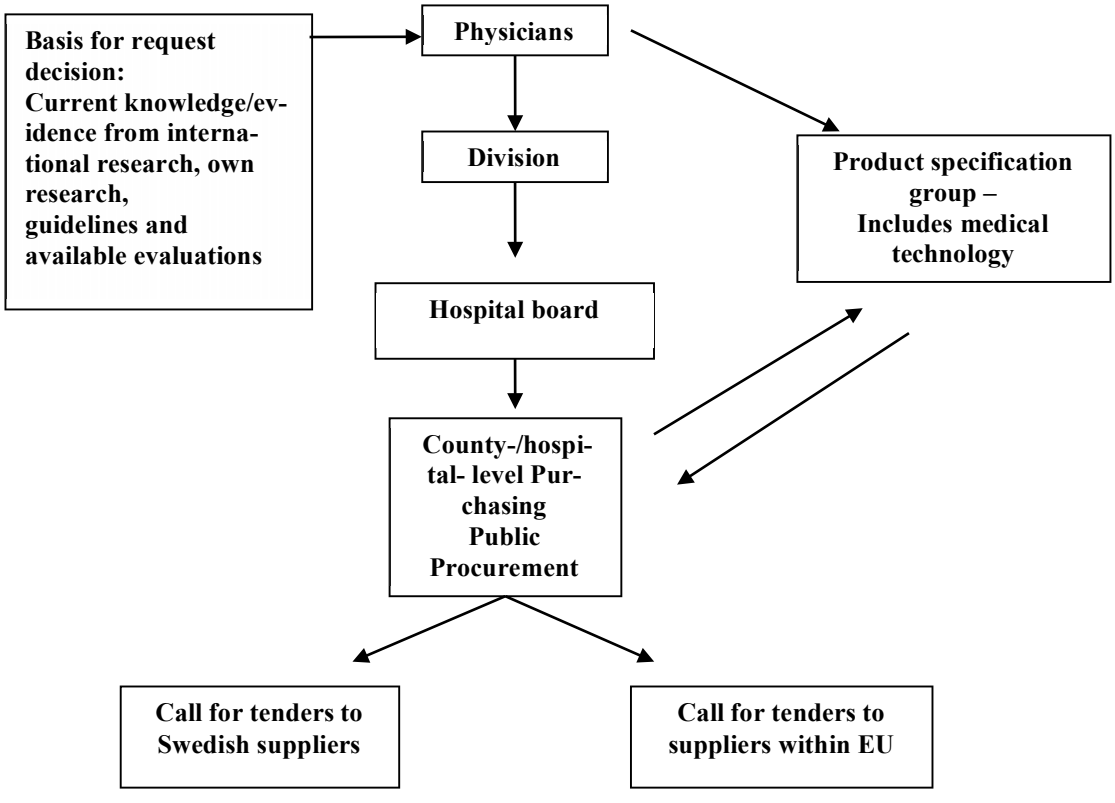

Figure 6. Purchasing procedure of medical technology

A purchasing process at a hospital normally starts at the department, which makes a request to buy a specific *new* device[42]. Requests from all hospital departments comprise a 'wish list'. Before the list is submitted to the hospital management, which has the ultimate responsibility for *purchase decisions*, all requests have to pass through divisional management (in case such exists). A divisional manager has the executive responsibility to approve or reject requests in accordance with the division's yearly budget (Vinsa, 2007; Häggman, 2007). Decisions are made in consultation between departments and divisional management (Häggman, 2007; Öberg, 2007; Ekbäck, 2007).

[42] New devices go through a different process from the previously established technologies that need to be replaced by a newer version or be updated.

It is pivotal that purchase decisions are not based on a random process or 'gut feeling'. Before any decisions are made on whether to invest in a specific new device/method or not, it has been subject to a thorough scientific review and an assessment of its 'performance' in relation to the existing methods in use at the specific department/using unit (Norlén, 2007; Malmberg, 2010a; Palmgren, 2010; Pedersen, 2007). Healthcare professionals have been arguing their case based on current knowledge from such as international research articles, evaluations made by central agencies (e.g., SBU) if these are available and sometimes research made at their own department. There is no such thing as a 'random process' or an 'opinion-based process'. Conversely, it is commonly a question of a partially scientific discussion and partially a discussion relating to the new technology/method to already existing resources considering, economic, technological and social aspects (even if healthcare personnel normally would not label the discussions in these specific terms themselves). Decisions are based on a professional discussion relating scientific data to the specific departments' capabilities and needs with regard to treatment options for their patients. Some hospitals perform 'mini-HTA'[43] as part of their introduction process for new devices. These are performed by the medical technology department[44]. Depending on the specific hospital's organisation, the medical technology department is involved, to a larger or smaller extent in most introductory discussions of new advanced technologies at the hospital. Final *purchase decisions* are thus made once a year by the executive management, who in turn have been informed of the underlying discussions and scientific material behind the request and also has taken into account the current needs of the county population in order to make priorities that correspond to needs in the population. Once the decision is made, the list of purchases is executed by the central purchase department. Hospital management sets the framework for each purchase, including factors such as price and quantity (Vårdanalys, 2015:2).

The purchasing department is then responsible for the ***procurement process***. A hospital is able to influence a certain purchase through the product specification[45] - a general contract that constitutes the foundation for procurement.

[43] HTA, Health Technology Assessment, where the "mini-HTA" represents local evaluations of the technology's efficiency in the specific purchasing context.
[44] Medical technology departments handle the technologies at a hospital. They normally control technical safety, and perform services but are also, to a varying degree depending on county, involved in the purchasing of new technologies.
[45] Specification of requirements is put together by a 'reference group' that typically includes one or more of the healthcare professionals that have requested the equipment in the first place,

However, the procurement process is per se formalised and the decision of which supplier, winner of the contract, is made by the purchase department. To avoid the risk that a physician/nurse could potentially prepare a product specification to best suit the manufacturer he or she prefers, specifications have to be outlined in general terms and be transparent in order to ensure that all suppliers have the same information and same opportunities to provide a suitable product and win the tender.

From a policy or 'systemic' point of view, procurement regulation is a way to uphold 'fair competition' between suppliers and generate lower prices for the public customer. This suggests that the product specifications of medical technology equipment must adhere to 'open' descriptions of a specific product/service without opportunities for discussions or negotiations. Until 2014, lowest price was the main indicator to be considered in any public procurement process. The EU however, complemented its procurement directives in 2014, giving indicators such as quality, environment, social influence and innovation an equally important impact (Van de Abeele, 2014).

In Sweden, public procurement is regulated through a specific law, LOU[46] (2007:1091), which was introduced in 1994 when Sweden became a member of EU with the corollary that public purchases above a certain threshold of value, from that point in time, were subject to open procurement within the whole EU. Generally, the law provides eight different primary procedures that can be utilised in public procurement. The two most common procedures are *open procurement* and *selective procurement* (Konkurrensverket, 2014). These two can be utilised for all procurement above the threshold value. In a common procurement procedure, product specifications are announced nationwide and within the EU at a 'board of specifications', after which suppliers can respond with their offers. Public procurement is a very formalised form of purchase, where there is more or less no space for interactive negotiation.

However, for purchases below the threshold value, there are two forms of procurement procedures[47] allowing for the seller and buyer to have a dialogue. An agency can, through these specific procurement procedures, initiate a dialogue with potential suppliers *before* initiating a tendering procedure in order to secure that the specific needs of the authority are catered for (Konkurrensverket, 2014). Yet the most common procurement procedures are open procurement and selective procurement.

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as well as technicians specialised in medical technology, and a representative from the purchasing department (Södergren, 2005; Berndes, 2005)

[46] *Lagen om Offentlig Upphandling "The Law of Public Procurement"*

[47] "Förhandlat förfarande med annonsering" (translates as 'Negotiated procedure with advertising') and "Konkurrenspräglad dialog" ('Competitive dialouge') 2007:1091)

Healthcare practitioners sometimes find the procurement processes frustrating since they do not have control over the equipment supply at their departments and clinics. The seemingly 'same' technology can differ in use, despite the fact that the technological features and outcome in treatment are, on paper, about the same. For example, open tendering and procurement procedures run over short time periods; normally a contract is valid for two years (Berndes, 2005, Södergren, 2005). Short time perspectives and a constant renewal of contracts is considered problematic from the perspective of healthcare practice. As explained by the head of central purchasing in Uppsala, Christina Södergren:

"If, for example, a department has used specific equipment one year and the next year decides to increase the existing holding by one piece, it is at risk of getting yet another manufacturer that better responds to the specifications in the contract."

The positive effects of a higher degree of standardisation in purchasing processes are mostly expressed by the administrative personnel with financial responsibility, who state that it has become easier to control both the amount and quality of new technology used in the provision of healthcare services. There is also a general satisfaction with the expanded tendering process within the EU, which some claim increases the amount of offers from suppliers and enhances the quality of services and goods (Södergren, 2005; Berndes, 2005). From a supplier's perspective, like ProstaLund, there is no possibility to interact with the direct users (physicians) at the departments when preparing a tender. Suppliers instead have to adjust to formalised aspects of the technology/methods they wish to sell. *Leasing* out an instrument used to be a way to avoid procurement, but today even leasing contracts have to go through public procurement. Via leasing, suppliers of medical technology were able to place a device in a clinic for free and then charge per treatment (Rosén, 2008). Leasing was available as an alternative to procurement until 2007, when the law was changed.

5.3.1 INNOVATION PROCUREMENT

Innovation procurement was a reaction to the fact that regular public procurement had been identified as a barrier to new and 'innovative' solutions to reach

end customers in public organisations (SOU, 2010:56). The purpose of innovation procurement is thus to promote innovation in public organisations. Before the introduction of innovation procurement, there was something known as *technology procurement*. The difference between these two types of procurement is that technology procurement provided for new technologies available in foreign markets and was focussed on technical solutions. Innovation procurement provides for the development of new technologies, services or goods not yet available in *any* market (SOU, 2010:56, Konkurrensverket, 2014).

A report on public procurement and innovation from the Swedish competition authority (Konkurrensverket) (2014), defines five categories of procurement;

- **Regular procurement**
- **Innovation-friendly procurement** – regular procurement focussing on functions instead of fixed features and parameters of the procured service or good.
- **Direct innovation procurement** – The procuring agency is the end user of the service or good coming out of the agreement.
- **Catalytic innovation procurement** - An agency coordinates the process and acts as a 'catalyst' between supplier and end-user with the main objective of supporting the end user.
- **Pre-commercial procurement** (which is not innovation procurement) - targeted procurement of R&D results and the development of prototypes, only available for private companies.

(Konkurrensverket, 2014, p. 9)

The different categories show that innovation procurement as such is not a clear-cut procedure and can take many different forms. It is also a question of defining 'innovation': within the frames of this categorisation, innovation denotes both incremental development of already existing services or goods as well as solutions of a more radical nature.

In the governmental report (SOU, 2010:56) on innovation procurement, the authors distinguish between innovation-friendly procurement and innovation procurement, with the former being a way to include innovative solutions in regular procurement, so as to make sure these are not disadvantaged. Yet, an innovation-friendly procurement does not necessarily have to result in an

innovation. Instead, innovation procurement demands innovation as an end product (SOU, 2010:56 pp. 145-146). Furthermore, innovation procurement is not a legal obligation but a *recommendation*. It creates an opportunity for agencies to procure new solutions that have not yet been commercialised and would not be offered in a normal purchasing tender. In the innovation procurement directives, the phenomenon of innovation is described as follows:

"Innovation intends, within the frames of these directives, a seminal combination of different resources in the shape of a value-enhancing offering, responding to a demand in a market"

and

"*Value-enhancing implies* [for the innovation] *the supply of value, which is most easily measured through the price mechanism. A buyer is prepared to pay for the value enhancement"*
(SOU, 2010: 56, p. 57)

The innovation is defined as a new solution that meets an unmet demand. The procurement process has to be guided by an existing demand for something that does not yet exist.

Innovation procurement is a way for a public customer to find an external development partner through a procurement procedure. It is thus a formalised process subject to competition rather than to build a relationship with an external partner (as seen in the business landscape). Instead, procurement and contracting will, through the mechanism of free competition, decide on collaborating partners. However, these kinds of contracts are under constant scrutiny, and collaborating partners can be changed on a regular basis. This process, with its continuous evaluations and possibility of switching partners, is unique to innovation procurement since there is no predefined product or service. It is thus held to be a uniquely flexible form of procurement (SOU, 2010:56; Konkurrensverket, 2014).

5.4 REIMBURSEMENT OF MED-TECH IN HOSPITALS - DIAGNOSIS-RELATED GROUPS (DRGs)

The use of new technologies/methods is often related to high costs, not only caused by the costs of purchasing the device but also due to the care processes that come from using a new device. Accounting for costs in the provision of healthcare services is complicated, especially in hospitals with complex care processes. How ProstaLund's device is reimbursed in the healthcare system is decisive for its chances of achieving widespread use. This section describes one of the most significant reimbursement models: DRG, *Diagnosis Related Groups.*

DRG is a patient classification system (PCS) to reimburse healthcare service in hospitals. Held to be one of the most influential models applied to medical financing during the second half of the 20th century, this system has been acknowledged as one of the major factors in the shift of both the economic and power balances between providers and financers of health services (Mayes, 2007).

DRG was first used by the U.S. government in 1983 as a means of reimbursing hospitals. As early as 1984, the first attempts were being made to adopt the system in Europe. Since then, DRG has spread quickly throughout the world (Mayes, 2007; Busse et al., 2011) and was designed as a prospective payment system to price healthcare and facilitate state reimbursement to providing units such as hospitals. Prior to DRG, the two most common ways to control providers and their payment was either through the reimbursement systems of *global budget* or *free for service*. The latter one risks overproduction of services, since there are no economic incentives for the provider to limit the services provided. Regarding *global budget*, politicians set an overarching budget for each providing unit with an expenditure ceiling, which is a way for financers of care services to control escalating costs. The global budget model is, however, at risk of insufficient provision of care services and of creating long waiting lists, since the providing unit lowers production in order to stay within budget. DRG is, then, held to be a tool that creates incentives for providers to increase the number of cases treated and reduces the number of services per case. In the DRG classification, patients are not viewed as economic units but are categorised into larger groups of cases. DRGs simplify an otherwise very heterogeneous population of individual patients into a standardised system of patient groups which have similar resource utilisation

and clinical characteristics. DRGs sets the maximum amount that can be reimbursed for a specific case. It implies that all the medicines, med-tech procedures and personnel costs to treat a particular disease case must be under the DRG limit or they will not be paid back to the hospital. The system is supposed to create incentives that neither under-provide nor over-provide services, but instead create incentives to enhance efficiency (Busse et al., 2011).

The DRG system is understood and applied differently in different countries. The northern European countries, including Sweden, have applied their own version of DRG under the name *NordDRG* (Linna & Virtanen, 2011).

Swedish healthcare has, since the early 1990s, been in search of an efficient way to reimburse services in the 'new organisation' of healthcare. Sweden has used global budgets to control costs and then DRGs to reimburse service providers. Hospitals each have their yearly budget (global budget) that only restrains the spending aspect. The main risk with cost ceilings is that, in order to keep within budget, the availability of care is lowered, which creates long waiting times for care. DRG was thus used as to increase productivity, decrease waiting times and also to generally enhance the quality of information and transparency in healthcare. The budget ceilings were still used to control costs and oversupply (Serdén & Heurgren, 2011).

The organisation of DRG takes place at two levels in the Swedish system. The National Board of Health and Welfare (Socialstyrelsen) is the central agency maintaining the case register in cooperation with the counties and regions that monitor the Swedish National Case-Costing Database. The counties and regions each register their case-costing so, consequently, there is a 'bottom-up' approach to settling cost data at a national level. The counties' different cost levels are averaged into a median value for each case. The work of The National Board of Health and Welfare is to validate the resource-homogeneity process between the counties that lay the groundwork for pricing at a national level (Serdén & Heurgren, 2011).

Since 1995, DRG's scope of use has been extended. The first version was adopted in 1995 by all hospitals, with the primary purpose of assessing performance and reimbursing only for inpatient care. The eleventh version, available since 2006, was used to reimburse, assess performance as well as benchmark and measure productivity. The latest (twelfth) version of the system is used to reimburse both inpatient and outpatient care, as well as rehabilitation, and the number of cases has grown from 500 to 976. Since 2010, DRGs have not only been used to reimburse somatic care but also psychiatry.

However, the counties are autonomous and the use of DRG is voluntary for each of them. When first implementing this system, the counties developed their own pricelists for cases. The national pricelist is recommended when counties price their care, but many of the large hospitals state that the level of the national pricelist is generally too low. Some hospitals apply a mix of national and local lists to price their care.

New innovative technologies have their own procedure and are given special attention in the administration of DRG. Most hospitals negotiate pricing of new technologies with the county before they can be adopted into the system. It is the rule that, before a new technology can be negotiated, it has to first be brought into use; from there, it takes about two years for the technology to be incorporated into the reimbursement system.

DRG is a tool for management to better understand, control and compare how resources are used and consumed in the system. It also offers a system to compare the levels of resources consumed for different diseases, departments and hospitals. One important implication of DRG for microwave technology is that it initially was used to reimburse *inpatient care only*. Microwave treatment is an *outpatient* treatment and therefore it often falls outside the boundaries of DRG classification, unlike the surgical standard procedure of TURP, which is an inpatient treatment and consequently was accounted for by DRG. Therefore, the two methods generated costs in different places in the accounting system, TURP within the limits of DRGs and TUMT/PLFT outside the limits, which results in an economic hindrance to its use in hospitals and has implications for the total costs of BPH treatment.

5.5 EDUCATION OF UROLOGISTS – THE KNOWLEDGE FOUNDATION OF THE PROFESSIONAL STRUCTURE

Specialist education of urologists is yet another aspect of importance for technology use. Education serves as the knowledge base and will affect the likelihood of new methods becoming embedded into use. It is a question of understanding the difficulties that might arise when old knowledge has to adapt to new knowledge and is pivotal in understanding change processes.

Physicians have had a strong influence in hospital organisation since the very infancy of organised healthcare, much of which is due to an inherent professional expertise that is difficult for a layman to question. Even in the current healthcare system, physicians constitute a strong profession with great

influence in the organisation, even though this position is becoming increasingly weakened. With the advent of NPM (see Chapter 4.2), there has been a tendency towards the de-professionalisation of physicians and the scholarly healthcare debate offered proof of professional knowledge being replaced by regulations, standardisation of practice (such as EBM or DRG) and efficiency measures. There has been a shift of power between providers of care and financers. (Blumenthal, 1994; Blomqvist, 2007; Reynolds, 1994; Evetts, 2009).

Meanwhile, an important prerogative of the profession concerns treatment responsibility. Physicians individually have the authority to decide about suitable treatment options for their patients. Hence, a urologist that feels more comfortable performing invasive surgery rather than manoeuvring a high-tech device will probably choose the method for which he/she has the highest skill level. A head of a hospital department and colleagues are, of course, able to exert influence on the choice of treatment methods used at a specific department – the available options are often collegial joint-decisions. Consequently, new methods have to be approved by the head of the clinic and commonly also by colleagues. However, with regard to choosing between the various *approved* methods at a clinic, the individual physician is always responsible for choosing the specific method with which a patient is to be treated. From this aspect, education becomes important for the possibilities of innovation to unfold in the provision of healthcare. Innovating in the provision of healthcare is influenced by both regulations and professionalism, with the latter closely connected with the education of physicians.

The education for urologists in Sweden consists of general medical school for five years, after which students go through their first practical training period (AT) in different hospital departments before choosing a specialty. The total time in education from medical school to becoming a specialist is about 12 years. The basic training follows the central guidelines of medical higher education and is under the responsibility of the Swedish National Board of Health and Welfare. The education to become a specialist is not centrally governed but handled by senior physicians of each hospital who train the students. However, there are central goals that have to be fulfilled for Specialist Training (ST) education, such as routine tasks or interventions (*Sveriges läkarförbund*, 2008; Carringer, 2008). Since 1993, the association SPUR[48] has controlled the quality of medical specialists' education. Broadly speaking,

[48] SPUR – *Sveriges läkarförbunds specialistutbildningsråd*

SPUR's purpose is to decide upon reforms in the specialist training of urologists, along with providing inspectors to certify the quality of specialist education. The overarching goal of SPUR is to work towards a larger homogenisation of specialist-training nationwide (SPUR, 2005). Generally, the goals of specialist education were renewed in 2008, but they had remained untouched, for over a decade (Carringer, 2007). Compared to the rapid development of new treatment methods and new technology, educational criteria tend to progress a bit slower. Still 'traditional' training is claimed to be an indispensable platform on which to build. In a surgical specialty, such as urology, taking the example of BPH treatment, the slowness of educational criteria becomes evident. This has to do with the necessary basic skills a surgeon needs to master. And here surgery is important under many circumstances; if, for example, complications arise during a non–surgical treatment, such as microwave treatment, surgery is often the only way to repair any damage. Surgical training is, then, the basic skill that all urologists need to master, independently of how routinised such treatment is, ranging from open-incision to endoscopic methods (Pedersen 2007, Norlén 2007, Malmberg 2010a, Broström 2010a, Wagrell 2007).

In accordance with current ST (Specialist Training) guidelines, urologists do not receive any training in manoeuvring technical devices like TUMT during their education or specialist training. ST in urology emphasises surgery since urology is a surgical sub-specialty. Urologists claim that PLFT is not as difficult as surgery. They also claim that accomplishing good and permanent surgical results demands training and, more importantly, an interest to learn and actively practise new methods. Among urologists, the attitude towards using microwave treatments such as TUMT or PLFT varies; it has, with an ironic undertone, been called:

"Penal servitude for young training physicians" (senior urologist, 2007)

Another comment was:

"Even if it was better, I would never use it because it is too boring" (senior urologist, 2007)

Microwave treatment often involves spending hours in front of a machine, watching curves and numbers on a computer screen and adjusting the catheter and temperature when needed. Especially during training, there is a need for

education in order to achieve decent treatment results with the enhanced TUMT technology (Carringer, 2007; Malmberg, 2010a; Broström, 2010a). Simple as it might sound, microwave technology demands knowledge that stretches beyond the boundaries of current education, such as understanding tissue destruction at certain temperatures, the individual needs of patients, the relationship between the size of the prostate and irradiation parameters, and how to place the catheter with high precision – all knowledge and skills that a urologist acquires with experience.

Urologists have to be skilled surgeons, which is why surgical procedures naturally constitute a large part of their specialist training. It takes time for new methods to enter an educational structure and they have to be both scientifically verified and embedded among physicians over a longer time period before entering into specialist training programmes. A SPUR inspector expressed that there probably could be exceptions to the 'slow changes' in educational goals and guidelines if there was a revolution of some kind in treatment, also stating that, so far, no such thing has ever happened (Carringer, 2007).

In the next chapter, we shall continue to scrutinise the work and procedures of four different hospitals and four different urology clinics that have all been involved in developing and using microwave technology in the treatment of BPH.

6. PROSTALUND AND FOUR USER-SETTINGS

The following chapter describes four different user settings that have used and or developed ProstaLund's TUMT device. Moreover, ProstaLund has had close collaborations with these four units and has tried to establish a continuous use and thus commercially embed their device. The hospitals are: Örebro University Hospital, Uppsala University Hospital, Lund University Hospital and Kalmar Regional Hospital. These are all public hospitals, two of them being large university hospitals, one a medium-sized university hospital, and the fourth a somewhat smaller regional hospital. These four settings were primarily chosen because they all took part in the development of PLFT. They all have, at some point in time, actively used or conducted crucial research on the PLFT technology.

All organisational levels will be accounted for, at least in the sense of attitudes towards both new technology and the control tools presented above. The structural rules described above will, in this chapter, be contextualised and described from the perspective of employees at each of the different hospitals. These four user settings are presented in the same way, to help the reader to understand how *the same structural rules* are operationalised in different ways within these diverse organisations.

6.1 ÖREBRO UNIVERSITY HOSPITAL

The university hospital of Örebro, USÖ, is one of seven Swedish university hospitals. With its 3,500 employees divided over 37 departments, it is a large organisation. Since January 2011, the hospital has provided higher education for physicians.

Örebro University Hospital

USÖ is one of those hospitals that provide wide-ranging care despite being located in a small county. Since activities at the hospital are far too comprehensive to be covered by tax income from the local population within the county, USÖ has to be competitive with other hospitals that potentially could offer the same kinds of services. Given these conditions, the hospital is run as a 'profit unit', which is compelled to sell specialised healthcare, mostly to adjacent counties.

Out of the total turnover of 600 million SEK in 2007, sold healthcare to other counties amounted to 350 million SEK, while healthcare covering the needs of residents within the county came to approximately 200 million. Hospital management seems somewhat unbothered by the competitive situation (which, at some other hospitals, is given a more intense focus), stating that it fails to see how the hospital can be in a competitive situation over customers (Öberg 2007). The hospital CEO in 2007, Öberg, has a quite pragmatic view of the 'competitive' situation and emphasises the simplicity of selling care

rather than focusing on competition, stating that the hospital sells most of its care to patients from neighbouring counties. Patients tend to choose Örebro hospital because it is the closest hospital to where they live. Because of this 'simple logic' and a continuous stream of patients from adjacent counties, Öberg argues there is no real need for marketing in the traditional sense (Öberg 2007). However, other voices at the hospital have a different opinion and say that management communicates both the importance of marketing and that the hospital need to sell a larger amount of healthcare to other counties. However, Öberg emphasises the importance of further developing the hospital's special competencies and becoming even better within these specific areas for which the hospital already achieves top results. Profiling the hospital's particular expertise in certain areas is held to be an important marketing tool (Öberg 2007, Frommegård 2007, Ekbäck 2007, Lindskog 2007, Carringer 2007).

6.1.1 ORGANISATION

In general, USÖ struggles to balance its budget and there is a constant and conscious effort towards higher efficiency. The hospital has a care quality support team supporting everyday activities. Any department in need of better organisation of its routines can consult the quality support team. This unit also works as an overarching support for the whole hospital during larger implementations or reorganisations, such as the implementation of new IT systems or other things that impact the organisation as a whole. Over the past four years, the hospital has introduced five new IT systems to enhance efficiency (Lindskog, 2007; Öberg, 2007; Frommegård, 2007; Carringer 2008).

The management's view of new technology and its possibilities of enhancing efficiency in the hospital is built on a consideration of the long-term adjustments and long-term effects. The management believes that new technology is one way to achieve higher efficiency of healthcare, but that normally it takes a long time to see the real benefits. The only way to quickly increase efficiency in a hospital with new technology would be to build a new hospital where the premises are adjusted to fit the new technology and processes are allowed to evolve around the new technology and not the other way round. (Öberg 2007, Frommegård 2007)

6.1.2 THE ECONOMIC ADMINISTRATION AND USE OF REGULATIONS

Since the beginning of the millennium, USÖ has undergone some fundamental changes in its organisation. Most of the changes concern the more extensive control in economic administration, but also changes towards a more rigid use of accounting principles (Frommegård 2007). The economic restraints and budget awareness had already, however, become more visible to all employees at the beginning of 1990, as illustrated earlier in Chapter 4.2. The new era of economic thinking pervaded the organisation and its personnel significantly. However, to carry out profound changes takes time in large organisations such as USÖ. In 2007, the hospital operated two types of performance measure; first, the more traditional statistics, such as measuring appointments per physician and days of hospitalisation per patient, etc. Statistical measures have long been utilised in public healthcare production as a measure of productivity and performance, even though statistics are increasingly said to not showcase the actual amount of resources consumed during a patient encounter (Frommegård, 2006). USÖ practices DRG as a performance measure for institutionalised healthcare, applying the national pricelist to price their care in accordance with national standards. The management at USÖ argues that the "non-scientific" part of everyday work at departments is the easiest to influence, through new work-routines and the documentation of activities where the most important aspects are financial reports and performance measures. Although managers consider it impossible to 'push' physicians in certain ways with regard to treatment methods or the use of new technology because of their sovereign position in terms of treatment decisions. (Öberg, 2007; Ekbäck, 2007; Frommegård, 2007; Lindskog, 2007).

Budgeting is another crucial aspect in grasping the mechanisms behind medical technology investments. With regard to the budget for new medical technology, the hospital has rather limited resources to make new investments. Most investments are made as replacements for old, worn out technology rather than any really new equipment. All technology investments (either new or substitutes for older versions) are debited on the same account. Also, since most of the old technologies form part of the fixed structure and have a given position in everyday activities and routines, the *already established* structure of technical equipment has the highest investment priority. Seldom is any money left to invest in totally new equipment. New technology investments are thus often made outside normal budget frames and financed by external means. This clearly puts division managers in a difficult situation, where it is hard to justify new technology investments when there is an urgent need for

the replacement of existing equipment (Öberg, 2007; Ekbäck, 2007; Frommegård, 2007).

The problem is often due to judging priorities on a 'horizontal' level: when all departments have had their annual share of reinvestments (renewal of old equipment), which department is to get the new technology investment? Such decisions often come down to choosing between the elderly and children, which is why financial priorities sometimes become ethical discussions.

6.1.3 ROLE OF EVIDENCE-BASED MEDICINE AND SBU

In its search for high-quality treatment, USÖ strives to use only evidence-based treatment methods. To ensure new methods are scientifically evaluated before being brought into use, all new practices are discussed by the physicians at the department. The physician arguing for a new method presents the results and evidence available. The decision is then in the hands of colleagues that make a joint-decision based on the available evidence and their prior knowledge (Ekbäck, 2007). The advantages and disadvantages of the new method are put under scrutiny in the collegial discussion, which forces the physician to dig deeper into the evidence to try and get it accepted by colleagues. In this regard, EBM is a tool that expands the collective control of the various methods in use (Ekbäck 2007; Carringer 2007; Pedersen 2007).

SBU's inquiries and recommendations are closely linked to the move towards evidence-based medicine at the hospital, and they can complete and support the decision-making process. Since SBU addresses aspects other than just medical, its inquiries are of importance in evaluating new technological methods. Consequently, EBM is always strived for and SBU reports are utilised as a tool to ensure standards. Still, some physicians at USÖ express their frustration over EBM as a slavishly followed system, regardless of the specific complications underlying some single-patient cases. Another downside is the extensive administrative work the system requires, which takes up a lot of precious time in an already-pressed schedule. Physicians at USÖ state that there are many pharmaceuticals that have been successfully used over long time periods that have now been withdrawn after being subject to negative evaluation. Situations have occurred where physicians find it difficult to treat their patients according to best practice while at the same time fully respecting the rules of the evidence-based system. Meanwhile, another camp of physicians might find such an argument contradictory; depending on the situation and circumstances, these kinds of contradictions between physicians' professional experience and evidence-based recommendations might occur. Under

special circumstances, there is the option of invoking 'escape clauses' that can circumvent the rules. Such work is, however, thought to be extremely time-consuming (Ekbäck, 2007).

6.1.4 THE ROLE OF RESEARCH AND EXTERNAL RELATIONSHIPS

USÖ does not have a tradition of conducting basic research. The hospital has only quite recently earned the right to educate physicians and thus establish a medical faculty, which in turn is a prerequisite to conducting research (normally, basic research is only conducted at university hospitals that have their own medical faculty linked to the university). However, *clinical research* is an activity of great importance for this hospital, not least to uphold its name as a university hospital. With a great emphasis on clinical trials, this hospital is at the cutting edge of developing new 'in-practice methods'[49]; even if it, this far, has not received governmental funding to conduct research, the county council has earmarked 70 million SEK each year for USÖ to conduct clinical research. The hospital's philosophy with regard to research is to address practical needs, so to develop better methods based on the requirements of everyday activities. There is no way to precisely tell how much clinical research has actually influenced everyday activities at the hospital, but physicians themselves state that many of the methods developed at the hospital are implemented into everyday practice. It was, however, also stated by the physicians that there is now less research cooperation with other hospitals than there used to be – something that was blamed on the competitive situation between hospitals and counties. Physicians stated that USÖ used to have more joint research projects with hospitals such as Akademiska in Uppsala, but that such cooperative projects have diminished since the hospitals became located in different financial districts. USÖ instead focuses on the internal situation and on conducting research based on its own needs (Ekbäck, 2007; Frommegård, 2007; Öberg, 2007).

6.1.5 THE UROLOGY DEPARTMENT AND BPH TREATMENT

The urology department is rather large given the size of the hospital, with 55 employees. BPH treatment at the clinic accounted for 8-10% of total activities in 2007, which equals approximately 400 patients a year (Pedersen, 2007).

[49] "In practice methods" refers to practice-based solutions able to facilitate everyday work at the clinics and enhance the efficiency of the provision of healthcare services.

PRODUCTS

At the initial stage, urologists most often medicate their patients for BPH to alleviate symptoms and avoid deterioration rather than cure the disease. At the next stage, which unavoidably is *active* treatment, USÖ practices TURP intervention, the surgical option, which is the traditional way of treating BPH. This was not the only option available in the active treatment of BPH in 2007. Until the end of 2006, it was possible to receive low-effect TUMT – the first version of microwave treatment that was developed in cooperation with ProstaLund at the beginning of the 1990s. But when Pedersen, who had been a leading user of TUMT (see section 4.3.1) retired in 2006, physicians made a joint decision to stop treating BPH with microwaves.

Urologists at USÖ argue that PLFT is *theoretically* a 'better' method than TURP, but not in practice, which relates back to experiences of complications in the aftermath of microwave treatment. These urologists claim there is a wide spectrum of things that can go wrong after microwave treatment, as opposed to surgery, where a urologist with his/her own eyes can see how much tissue is left and better forestall complications (Pedersen, 2007; Carringer, 2007).

FACILITIES

The urology clinic at USÖ is independent in the sense that it does not belong to any larger surgical department and is – as are almost all departments – divided into clinic and ward sections. On top of that, this department has its own surgery theatres, which means that urologists do not have to compete with other departments over surgery hours. The fact that the clinic has its own surgery facilities gives it a large logistical advantage. Surgery hours tend to be one of the larger bottlenecks in the provision of healthcare. However, to perform surgery, anaesthesia is essential and is done in a central department, serving the whole hospital. On the other hand, microwave treatment demands examination rooms where the intervention can be performed and these are available at the clinic. The examination rooms are commonly used for examinations and simpler diagnostics such as blood tests. Surgery premises are used for one purpose, i.e., surgical interventions, whilst examination rooms have many more different functions (Pedersen, 2007; Carringer, 2007).

ORGANISATION

After the development of the first TUMT device in 1992, the department continued to use microwaves in BPH treatment, although not as extensively or

even in the same way as it had initially planned. The clinic had, at the beginning of the 1990s, reduced its BPH surgery by 20% thanks to TUMT treatment. In 1992, surgery accounted for 252 treatments a year, while in 2006, the range of treatment options and diagnostics had changed somewhat and surgery was reduced to 80 treatments a year; new pharmaceutical treatment was the principal reason for this shift. The older version of TUMT was used until 2006 and, in 2005, the clinic also leased a newer PLFT device (Carringer, 2007; Pedersen, 2007; Carringer, 2008).

What is interesting is *how* the old device – a low-effect TUMT device – was utilised until 2006, it was used to treat prostatitis, but not BPH [50]. This new area of use arose as TUMT was found to have good effects on smaller inflammations in the prostate. Pedersen, being one of the developers of the first ProstaLund low-effect device, of course had a vast knowledge of its functions and beneficial use and developed an area of use for which low-effect TUMT was actually perfect. In reality, Pedersen had rather quickly noticed the insufficiency of low-effect TUMT in BPH treatment, and claims to have made himself rather unpopular among TUMT supporters in the mid-to-late 1990s when he lectured that microwave treatment would never be able to replace traditional surgery for the aforementioned reasons. The hospitals that had a great belief in the TUMT technology responded with incredulity (Pedersen, 2007; Carringer, 2007; Carringer, 2008).

When Pedersen retired in the spring of 2006, microwave treatment for prostatitis went out the door with him. He had been the only urologist interested in the method and therefore practically the only one treating patients with it. With Pedersen's retirement, USÖ's urologists made a joint decision to stop leasing the PLFT device in the spring of 2009. Additionally, after Pedersen's retirement, between 2006 and 2009, the use of microwaves in BPH treatment generally was very limited at USÖ. What, then, were the central reasons behind the abandonment of a method present at the clinic for almost two decades?

From more than one perspective, the usefulness of the technology seemed to have run its course. The decrease in microwave use at the clinic between the years 1995 and 2005 was not only associated with improvements in medication and a decreasing need for active treatment, it was also very much linked to the fact that no physicians, experienced or in training, were really interested in the method. This lack of interest combined with individual

[50] Prostatitis is an inflammation in the prostate, a less severe condition than BPH.

physician's treatment responsibility meant no physician was even able to recommend microwave treatment to their patients – a rather logical consequence, given that no physician will recommend to their patients a method they do not fully understand (Carringer, 2007; Carringer, 2008).

Urologists at USÖ reasoned that operating a PLFT device demanded a certain 'touch' in order to achieve results equivalent to surgery – something that was gained only after comprehensive training. In comparison to surgery, it was indeed a shorter learning process, but learning PLFT to a basic level was not enough to achieve results equivalent to those of surgery. A genuine interest is required to become an accomplished urologist in microwave treatment and, at this clinic, there was simply no one interested enough (Carringer, 2008; Pedersen, 2007).

Even if urologists had been more interested in treating with microwaves, there were still other obstacles, such as the difficulty of making PLFT a part of everyday activities at the clinic. Starting up PLFT as a general form of therapy would have led to adverse consequences for the whole clinic and its working routines (Carringer, 2008; Pedersen, 2007). An implementation of PLFT would have required more than one physician to operate the device in order to cover all work shifts. Each shift has to be covered by at least one physician able to treat with microwaves, which would require a large educational effort by everyone, including nurses. This would also increase costs to the clinic, in addition to those relating to equipment and treatment (Carringer, 2007; Pedersen, 2007; Carringer, 2008).

At a larger hospital, such as the one in Örebro, a personal interest by a single urologist is required to become skilled and use the method. At a smaller clinic, it is rather a problem of the quantity of patients and urologists available: less specialisation and a broader spectrum of diseases to cure makes it impossible for these urologists to achieve the same results as a specialist at a large hospital (Carringer, 2007; Pedersen, 2007; Carringer, 2008).

One of the strongest arguments in favour of the method is that it is better suited to elderly patients who are unable to undergo surgery due to the increased risk from anaesthesia. However, the staff at USÖ, considered this group to be far too small for PLFT to become cost-efficient (Pedersen 2007; Carringer, 2007; Carringer, 2008).

RELATIONSHIPS

The relationship between the clinic and ProstaLund developed in the early 1990s and serves as a good example of how external relationships are essential in research collaborations. USÖ's urology clinic was in this collaboration

more of a scientific lab, offering feedback to ProstaLund, while at the same time being a customer of this new technology. It was a question of mutual adaptation, between ProstaLund and the urology department at USÖ. The involvement of different kinds of departments, such as the medical technology department, which had knowledge about Bolmsjö's competencies in microwave technology and mediated the contact, but also contributing with their unique knowledge during the development (see Chapter 4.3.1). There was Pedersen as chief physician, pushing the project forward, but without the help from a range of different departments and people with specialised skills, the first TUMT device may not have been built (Carringer, 2007; Pedersen, 2007; Carringer, 2008).

6.2 UPPSALA AKADEMISKA UNIVERSITY HOSPITAL

The university hospital in Uppsala is one of the largest and oldest hospitals in Sweden. As a regional and university hospital, Akademiska serves multiple functions, providing both highly specialised care, higher education of physicians as well as extensive research activities. In its function as a university hospital, it has a tradition of conducting research, both basic and applied (Haglund, 2007). The many connections to other research departments and faculties within the university make Akademiska an important platform for all kinds of research. The 7,000 employees are divided into 7 divisions and 35 clinics. Each division has a manager with ultimate responsibility for all economic activities undertaken within the division (Vinsa, 2007; Suurküla, 2007; Haglund, 2007).

View over hospital area of Akademiska

When financing and responsibilities for healthcare was decentralised to the counties, Akademiska found itself in a rather difficult situation. Located in a small county with only 300,000 inhabitants, the hospital's activities and expenditure considerably exceeded the income provided by the small allocation base in the county. As a consequence, Akademiska was forced to sell healthcare to other counties in order to ensure that income will cover expenditure. In 2008, it was the single largest provider of healthcare in Sweden. In 2007, it sold healthcare amounting to 1.5 billion SEK. Highly specialised healthcare is primarily sold to neighbouring counties not large enough to provide internally for highly specialised treatments (Tufvesson, 2007; Suurküla, 2007).

The market logic, introduced with the NPM reform, means that all counties are free to contract with any available supplier within Sweden, private or public. Therefore, there is considerable pressure for the Uppsala Akademiska hospital to achieve new contracts and maintain the old ones as the contracts run over short time periods and there is never any guarantee they will be renewed. This creates insecurity about subsequent years' incomes and the constant effort to sell health services is very open and visible at Akademiska.

The hospital's management in 2007 had an explicit strategy to turn the hospital into a strong brand (Suurküla, 2007). The executive management at Akademiska argued that the hospital lives in a reality where it, on an everyday basis, has to be aware of the pressure of competition from other healthcare providers. Its competitors are all university and regional hospitals throughout the country. This pressure has resulted in a conscious shift towards higher cost-awareness throughout the organisation, where all employees should strive towards the same goal. One of the ways Akademiska is building its brand is through media exposure, in order to become the hospital on everyone's mind (Suurküla 2007).

Executive management, however, also calls attention to the difficulties in building a brand in the public sector, explaining that it is hard to control a brand given that the organisation is politically dependent. Even though, under normal circumstances, policies are on the whole not contradictory to the organisation's goals. Thus, new technology is not only important in the rationalisation of healthcare, but it also plays a decisive role in communicating Akademiska as a hospital at the cutting edge of modern technology with highly skilled physicians. Such marketing gives hospitals more external customers, from other Swedish counties or even from abroad, so they can cover the high costs that a hospital of this magnitude accrues (Suurküla, 2007).

6.2.1 ORGANISATION

Because of the difficult economic situation at Akademiska, being a large University hospital located in a small county, the efficiency of healthcare provision is of great significance. The management, furthermore, has a firm belief in new technology's capacity to rationalise provision. But, at the same time, the management emphasises the difficulties in implementing new technology, referring in particular to older methods living alongside new ones thereby creating inefficiency (Suurküla, 2007; Vinsa, 2007; Haglund, 2007). Two methods living alongside each other are a clear example of inefficiency that results in the waste of resources and prevents new technology from becoming properly implemented. Bringing a new technology into use implies that the older technology has to be abandoned; it is a question of reducing the number of available methods as part of rationalisation and keeping costs down (Vinsa, 2007). On a management level, technology is viewed not only as something that is able to rationalise activities at the clinics but also as an important tool in handling competition and being at the forefront of treatment offered to external customers (Suurküla, 2007).

6.2.2 THE ECONOMIC ADMINISTRATION AND USE OF REGULATIONS

Budgeting is not an easy process within large healthcare organisations. The overarching responsibility belongs to the politicians sitting as elected representatives in the county council. These politicians settle the budget ceiling once a year. Budgets do not vary much from one year to another, usually with small increases based on appreciations on the counties' and the municipalities' estimates for the upcoming year. The hospital's top management settles the budget, which is based on of five main perspectives: customer, market, personnel, economic processes and research & development.

Parts of the budget serve as an activity plan, which is why the *customer*, *market*, *personnel* and *R&D* parts of the budget are handed out to all personnel to support production. The purpose is to entrench the unitary goal of the organisation and reinforce the brand so that everyone feels they have a crucial part in building it (Suurküla, 2007).

Two budget frames are made for each division: one for *revenues* and one for *costs*. It is possible to divide the budget into these two different frames since the organisation does not have any profit responsibility. When the hospital board sets a budget proposal for each of the seven divisions, frames are negotiated with each division, after which the board is able to set an overall budget (Tufvesson, 2007; Tufvesson, 2008; Vinsa, 2007; Suurküla, 2007).

As a public institution, the Akademiska hospital is not a profit-driven organisation, making it possible to steer both the hospital's revenue and costs, which is a deliberate decision by management (Tufvesson, 2007). Not having to steer each division or clinic towards a zero-balance facilitates the transparency of income activities and is argued to be more efficient since it forces clinics to provide well-founded calculations of their potential income from each activity without weighing revenues against costs. This approach to management control also enhances reliability and opens up for possibilities for discussions of the amount of services produced. In turn, it is crucial to Akademiska to have high reliability of its income calculations since a large part of the income relies upon sold healthcare to other counties (Tufvesson, 2007; Ekström-Boström, 2007; Suurküla, 2007).

Each division has its own frame for costs and income. Costs are discussed within settled frames; the same goes for income. Since the organisation does not strive for profit, investments are not made to make larger profits, but rather to enhance efficiency and allow the hospital to grow in size and knowledge (Tufvesson, 2007; Vinsa, 2007; Ekström-Boström, 2007). In turn,

the departments do not use balance sheets; only incomes and costs are registered without any budget responsibility, meaning that a department is not allowed to buy equipment on its own initiative; all transactions go through divisional management that approves or rejects all purchase requests. However, as long as investments fit within given frames, departments are free to choose their equipment and methods. Divisional management also emphasises continuous dialogue between the departments and the hospital management (Tufvesson, 2007; Häggman, 2006; Vinsa, 2007).

Uppsala Akademiska applies DRG to inpatient care (as of 2007), but only for patients from within the county. All outpatient care was still accounted for with traditional pricelists, meaning there was a fixed price for each treatment or encounter. There have been discussions at a managerial level about changing the pricing system of outpatients to DRG as well; management and the financing body (the county council), however, concluded there was too much uncertainty in the evaluation of different cases to employ such a strategy just yet. For sold healthcare, Akademiska employs a specific price list, to price all 'out-of-county' patients. The pricelist is split into inpatient and outpatient care (Tufvesson, 2007; Tufvesson, 2008).

The direct effect of the different accounting systems might bring forth the realisation that the economic benefits of technology use can sometimes be difficult to account for. The same disease might have different treatments accounted for on separate accounts, thus causing economic effects in both systems, but the total effect of one and the same disease in a hospital organisation might be difficult to assess. This fact potentially complicates financial comparisons and evaluations when investigating specific diseases and the diverse economic effects of each treatment method. A method like PLFT, which is an outpatient treatment, should consequently be accounted for on another system than the surgical treatment, TURP, which falls under inpatient care and DRG.

6.2.3 THE ROLE OF EVIDENCE-BASED TREATMENT AND SBU

The role of EBM is seen in a somewhat different light in a hospital like Akademiska, with a strong research tradition, which creates the foundation for evaluation and evidence. New methods are often up for clinical trials at such hospitals and physicians find themselves with an obligation to try out new methods (Haglund, 2007). The policy and role of new methods and EBM varies between departments since Akademiska is such a large hospital, but, in general, physicians have autonomy in conducting research as long as it is kept within the set budget for the clinic.

Many methods in use at the hospital are still undergoing trials. One can argue that Akademiska is a hospital where methods become certified, and tested in a scientific environment. The sense of high quality in the research of the organisation is very present. (Haglund, 2007; Häggman, 2007; Norlén, 2007) In cases where trials have not been undertaken at Akademiska, SBU evaluations play a significant role in promoting new methods (Häggman, 2005).

While SBU reports give good indications on diagnostics and treatments, they are by no means coercive; SBU inquiries are often used as help or support for particular treatments when needed. However, they do not have the same decisive role as is found at other hospitals (Häggman, 2005; Häggman, 2007). The closest thing to evidence-based methods is a yearly internal audit at each clinic. It is called 'quality registration and evaluation', and it is where basically one physician at each clinic is responsible for conducting the internal audit and compiling a list of all the methods in current use and evaluating each of these methods from a holistic perspective (Häggman, 2007).

6.2.4 THE ROLE OF RESEARCH AND EXTERNAL RELATIONSHIPS

Research has always been important at Akademiska and the activities at the hospital are, to a large extent, interconnected with other research institutions at the university. Research is an important cornerstone for this hospital and it is not unusual for physicians with research pretentions to beat a path to Akademiska's door. Research is further claimed to be the means to reach the goal of being a hospital at the cutting edge of healthcare provision, and has become mandatory for physicians who want to climb the career ladder at the hospital (Suurküla, 2007). A PhD degree is the minimum educational level to achieve a chief physician position, which is not necessarily the case at other hospitals in Sweden (Haglund, 2007; Suurküla, 2007).

Research is financed partly by the government through ALF[51] money, while the county contributes an equal amount each year. All university hospitals get ALF funds to support basic and clinical research and to assure the quality of medical school education. The ALF money is distributed among departments according to a distribution key based on the numbers of PhDs and dissertations each clinic produced during the previous year. Parts of the county

[51] ALF money is centrally governed research funding, handed out by the Swedish government to counties with University hospitals as compensation for providing medical schooling and conducting research. The money is divided into two separate income items. (*Sveriges kommuner och Landsting*, 2008).

money are allocated to development projects that do not concern research within the hospital, which is why it is hard to estimate the exact amount directly put into research (which also raises the question of the definition of research itself). Except for centrally financed research (ALF), there are physicians at Akademiska conducting *commissioned* research, even though the research manager at the hospital considers it a waste from a scientific point of view. Meanwhile, he states that there are exceptions even in commissioned research for a handful of projects that have produced scientific breakthroughs (Haglund, 2007). In the hospital's constant effort to stimulate pioneering research, it has put together groups of specialists with the aim of sifting out the most valuable projects. The final responsibility always lies with the individual physician or researcher to only take on projects of high interest with possibly cutting-edge results (Haglund, 2007). To consolidate the importance of research, executive management developed an annual balance sheet of research that was used for the first time in 2008. The intention behind this was to make research more visible to a broader group of co-workers and thereby facilitate the implementation of new findings and results into the provision of healthcare (Haglund, 2007; Häggman, 2007; Norlén 2007).

A substantial part of clinical research is done in cooperation with external partners, be it other institutions or private companies. In the case of microwave technology, the PLFT device is a clear example of a renowned research clinic, such as the urology clinic at Akademiska, which acted as a platform to consolidate the scientific evidence for microwave treatment. The technology had been developed at several hospitals before, but to really entrench its scientific value, it needed to be verified by a university hospital in a renowned scientific environment (Haglund, 2007; Wagrell, 2007; Häggman, 2007; Norlén, 2007).

One of the important external relationships of the Akademiska hospital is with central purchasing, which is external to the hospital. It is still part of the same county, but the two are now separate organisations. The cooperation runs smoothly and, from a managerial and administrative point of view, the new system of competitive tendering has increased the possibility of better controlling purchases and costs. Before the new competitive system was implemented, physicians were able to order and buy equipment directly from the department and choose between suppliers, which made it practically impossible to control the purchase of equipment and the cost to hospitals (Södergren, 2005; Vinsa, 2007).

As pointed out above, it is pivotal to understand the role that research has at larger hospitals, especially university hospitals. The financial value of

the *direct use* of research is not the foremost consideration that physicians have when conducting their trials; research has a value of its own for physicians and the hospital. The production of scientific papers is a part of an academic career that generates further research funding from sources that are both external and internal to the healthcare system. It is possible to discern a distinction in comparison with, for example, USÖ, where clinical use is prioritised over producing academic papers. Both approaches fulfil important functions given the specific organisational prerequisites and demands that are found in each context. However, from a managerial perspective, the aim of research is to enhance the clinical utility of research results, enhance economic efficiency and uphold good standing for Akademiska in competition with other hospitals (Haglund, 2007; Suurküla, 2007; Norlén, 2007).

6.2.5 THE UROLOGY DEPARTMENT AND BPH TREATMENT

At Akademiska, the urology department is considered to be rather small in comparison to its other departments. Urology is a narrow area of specialisation. In total, the department employs 70 people, of whom 14 are urologists (Häggman, 2007). This department's clinic has about 7,200 patient-visits every year, of which 500-600 patients are treated for BPH, or about 7% of the total.

PRODUCTS

BPH is mainly treated with medication, but the two active treatment methods available are TURP and PLFT, even if the frequency of active treatment overall has decreased. In the first half of the 1990s, about 250-300 patients a year went through active treatment of BPH, while in 2007 that number is down to 100-150 patients a year. Some urologists believe there are many patients being treated with medication in cases where surgical treatment would be more suitable (Häggman, 2005; Häggman, 2007; Johansson, 2007).

PLFT was, as described above, further developed at this department, where extensive clinical studies were undertaken (Wagrell, 1999; Johansson, 2008). This mainly clinical project resulted in a dissertation, which suggested that there should be some kind of scientific knowledge base concerning microwave treatment and a 'best practice' at the clinic. However, only a couple of urologists currently offer patients microwave treatment.

One obstacle to active use of this technology at the department is the fact that the urologist who initiated the development and conducted the clinical trials left the department in 2000. When the PLFT study was undertaken

back in the late 1990s, there were already antagonists among the physicians that did not like the method and who did not see its advantages over traditional surgical treatment. Today, the department still uses PLFT, but only a couple of urologists use the PLFT method as an alternative to other treatments (Johansson, 2007; Häggman, 2005; Norlén, 2007).

FACILITIES

The department is divided into a reception where patients can do check-ups and examinations in day care and a ward for patients in need of hospitalisation. The department does not have its own surgical premises. Surgery is performed at a central surgical facility, which is utilised by all clinics at the hospital. The urology department buys surgery hours from the central surgery department, where anaesthesia is included in the contract. Many departments compete for surgery hours, and it is fair to say that central surgery is something of a bottleneck (Häggman, 2007). To cope with the high burden, the hospital has outsourced most of the smaller interventions, like TURP, to other organisations. As a result, all TURP surgery is performed at a hospital in Enköping – a smaller city located 50 kilometres from Uppsala, but part of the same county. All other routine surgery in urology is outsourced to another small hospital, Samariterhemmet, which is located in the city centre of Uppsala. Depending on the type of surgery, different tariffs are charged; normally there is a 4-point scale to classify interventions, where 4 is the most expensive. A normal tariff for a '2' surgery is 300-400 SEK per minute (Tufvesson, 2008; Häggman, 2007; Johansson, 2008).

The fact that all inpatient operations are outsourced to smaller hospitals within the county means that active BPH treatment does not take place at the main hospital. There are, then, two active treatment options for BPH at this clinic, one outsourced and the other (PLFT) that is supposed to be done at the outpatient clinic at the hospital. The dilemma the physicians stand before is weighing the two alternatives, both from a professional point of view but foremost from an economic perspective, which complicates the picture somewhat. If the alternatives have more or less the same outcome for a patient, which method is to be chosen (Johansson, 2007)?

ORGANISATIONS

The cost of running this department far exceeds the total income by about 50% (Häggman, 2007); the county pays the difference. As long as the department does not spend money outside its given budget, it is free to distribute the

money according to its own judgement and expertise. There are not any specific measurements of efficiency in the everyday work of the department. The most common way of handling efficiency questions is through the regular statistics, the measurement of the number of operations and the number of days for institutional care. Another common way of determining efficiency is to calculate *care time per patient*. Care time for each patient was, in 2005, deliberately shortened to increase efficiency, yet there is no common view of how efficiency possibly could or should be measured at a department like this (Häggman, 2007; Häggman, 2005).

The routines are, in general, completely dependent on each individual physician and how he or she chooses to organise work. Physicians have their own methods and routines, to which nurses and other personnel need to adjust (Häggman, 2007). There is of course the possibility of agreeing upon some standardisation in the case of, for example, some types of diagnostics, but there is no requirement to conform to standardised treatment methods at this department (Häggman, 2005).

The urology department has adopted a 'close-to-patient' system, which means each physician follows his or her patient through the different steps in treatment. The same urologists perform the examination, diagnostics, treatment and follow up for each patient. Since not all urologists at the department practise PLFT treatment, patients' options vary. Physicians should always recommend the best treatment available for individual patients, but as is the case with most urologists at this department against PLFT, they would hardly recommend the method. Still, a patient is always entitled to request a certain method and there are patients requesting to receive PLFT treatment. Some physicians state that the biggest problem is that it is too rigidly looked upon as a *single* treatment option; urologists with a positive attitude towards PLFT advocate a treatment mix, while opponents advocate surgery as the only feasible treatment option (Johansson, 2007).

Looking back at the time when PLFT was accepted as a research project at the department in 1998, there has long been a history of aversion towards the method at Akademiska hospital. Norlén, who was head of the department in the late 1980s and also in 1998, refused to use the first TUMT method because it lacked scientific data. He was proven right in his suspicions when the method was not able to live up to its promised standards. But, when new data was submitted regarding the further developed technology of PLFT, he changed his mind and gave microwaves a second chance as a research project (Norlén, 2007). Still, given that each physician has his or her own personal interest, it is generally hard to introduce a new method to become a standard

procedure. It even turned out to be difficult to make urologists try out the new method, despite them having a large amount of research and knowledge available at this department (Johansson, 2007; Norlén, 2007; Häggman, 2005; Häggman, 2007).

As a research project, PLFT suffered from a few impediments to being accepted at the department. The research focus of the department also creates an extremely individualistic environment, where physicians advocate for their own choice of treatment methods and do not play a significant part in research if they do not perceive a personal interest in doing so. In addition to self-interest, it is also a matter of capability and reliability, that is, some physicians do not believe in the microwave method and stress its poor clinical results. Others, who had good training in using the method, say it fulfils a function as part of a treatment mix (Johansson, 2007; Häggman, 2007; Norlén, 2007).

RELATIONSHIPS

One issue, as concerns private/public development of new devices, in an academic context, is the scepticism towards biased results, meaning that the company have economic interests that can colour the research results, in favour of the company and due to underlying economic interests. In such research-heavy environments as Akademiska, many physicians conduct research with equipment developed in between healthcare and private business. This fact can bring about scepticism among colleagues questioning whether the project leader had any economic self-interest in the project. During the clinical study of PLFT in Uppsala, ProstaLund arranged a symposium where urologists were invited to ask questions and familiarise themselves with the method. They also arranged a demonstration and the urologists involved in the project presented their results. During one of these presentations, the project was criticised for only presenting the positive aspects of the results (Norlén, 2007). Even if the physicians presenting the results had not experienced any complications, there were other urologists at the clinic that had tried out the method and experienced problems in treatment; these urologists felt their criticism was not adequately considered, which explains why some scepticism arose (Norlén, 2007; Wagrell, 2007). This case clearly shows how projects very quickly can lose credibility when not paying attention to diverging incentives within a project.

6.3 LUND UNIVERSITY HOSPITAL

Located in the region of Skåne, Lund University Hospital is one of the largest university hospitals in Sweden and, like Akademiska, the hospital has a long tradition of research. Much of the highly specialised healthcare that is only provided at a few places in Sweden is performed in Lund.

Lund University Hospital

Until quite recently, it was an independently governed hospital but, due to reorganisations aimed at improving efficiency in healthcare provision, it has merged with the second largest university hospital within the region: Malmö University Hospital. From January 2010, the hospitals have been run as one organisation, even though they are geographically separated by 30 kilometres. Together, the hospitals employ about 12,500 people and have a yearly turnover of 10 billion SEK. Before the merger, Lund had about 7,800 employees.

The region of Skåne is rather large and densely populated, which is why the allocation base of taxpayers is almost sufficient to provide for most of the cost of healthcare at this hospital. Therefore, the larger hospitals are not *forced* to sell healthcare to other counties. Still, hospitals of the size of Lund and Malmö provide unique specialisations not found elsewhere in Sweden.

Financially, Lund University Hospital is not as dependent on selling healthcare to other counties as is, for example, Akademiska. However, as the executive manager of Lund University Hospital in 2009, Christensen, upheld the importance of selling highly specialised healthcare. Hospitals in Skåne feel a strong pressure to compete for their personnel from Riks Hospitalet in Co-

penhagen, which offers much higher salaries. Skåne tries to meet this competition by offering better working conditions and keeping its skills and knowledge on the cutting edge (Christensen, 2009; Cederholm, 2010).

6.3.1 ORGANISATION

To keep the budget in balance and cope with a large deficit, a new CEO was appointed in 2004, Christensen (Närlid, 2011). In 2009, Christensen introduced 'lean production'[52] – a new way to organise a more efficient provision of healthcare. His idea was that production of healthcare is driven by the same logic as production in any other organisation. When confronted by the suggestion that healthcare is not a production industry like any other, he vehemently states that there are few businesses that are as easy to standardise as healthcare (Christensen, 2009).

Introducing 'lean' healthcare to the departments meant using process charts for all activities and all personnel were supposed to take part in a constant effort towards process improvement. Lean production permeates the whole organisation and focuses on productivity, through both small and large changes. Christensen says that personnel in general are content with the changes lean production has brought about. However, some critical voices are witness to the dangers associated with tighter budgets and a strong focus on efficiency, which can be a danger to departmental research since an increasing share of activities are focused on production and fewer resources are left for clinical research (Bolmsjö, 2009) (Christensen, 2009; Malmberg, 2010a; Broström, 2010a).

The second step of the reorganisation of the county was the merger of hospitals within the Skåne region. As mentioned above, Lund & Malmö's university hospitals merged in January 2010 under the name Skåne University Hospital. But the merger also includes other hospitals, comprising the five largest hospitals within the region. The region shares physicians who are utilised in specialised ambulating teams. This means that a physician could be working in Lund on Monday, Malmö on Tuesday, and Ystad on Wednesday

[52] Lean production in this context is not equivalent to the concept of "lean production" as referred to in business administration literature (Womak & Jones, 1994). Even if authors as Pettersen (2009) concludes that there is no proper consensus as regards the concept lean production on a theoretical level there are yet common traits that defines lean production theoretically. The version adopted in region Skåne is however quite far from any theoretical conceptions of lean production, see for instance: Womak & Jones, 2003; Cooney, 2002; Cusumano, 1997; Dankbaar, 1994.

(see map of Skåne below). (Broström, 2010a; Malmberg. 2010a, Christensen, 2009).

Map of Skåne

Even if the policy has changed over the past two decades, the cutbacks, rationalisations, pushes for higher productivity and higher financial awareness have all been a constant feature of the Lund hospital in different shapes and forms (Malmberg, 2010a; Broström, 2010a).

The role of new technology in a 'lean' healthcare organisation is to rationalise the process/production chain. From a management perspective, it is important to organise activities around the new technology in order for activities to run smoothly. Christensen mentions there have been reorganisations to facilitate technology use, thereby making processes run smoother and diminishing patients' wait times. Instead of moving a patient around diverse departments (e.g., for x-ray or scanning, specialist physicians, etc.), the various steps of treatment are organised around the technology, where the patient is like a 'product' going through the different stages, but without so much waiting time. To facilitate these processes, healthcare strives to divide them into smaller, standardised tasks, preferably performed by different physicians and nurses who specialise in a few specific tasks. This is, however, an ideal picture and is not really representative of the actual work undertaken every day at the

hospital in Lund. Meanwhile, in some departments, they have succeeded in rationalising their activities through more efficient processes in line with lean production logic (Cederholm, 2010; Malmberg, 2010a; Broström, 2010a).

6.3.2 THE ECONOMIC ADMINISTRATION AND USE OF REGULATIONS

The Lund hospital has a budget ceiling, as has each division and department. Each department has its own cost frame where 60% of the refunding is variable and the remaining 40% is fixed. Lund University Hospital has a reimbursement system where 60% of the variable segment is performance related, while 40% is fixed. Management retains 1% of the fixed refunding as a motivation to not exceed the set budget and, if clinics succeed in keeping costs within set frames, management refunds the 1%. Management constantly stresses the importance of cost-control since there is little room for adjustments under the prevailing circumstances (Cederholm, 2010; Christensen, 2009).

Skåne was one of the counties that first used a purchaser-provider model (described in Section 4.2 above) with a decentralised structure. A total of 11 districts within the region were autonomous. However, the organisational and structural effects for which the policy had been designed did not occur: the purchaser did not have the mandate to make changes to organisational structures and production processes within the providing organisation. Additionally, the monitoring incentive for the purchaser did not have the impact on production processes that policymakers had hoped for (Pfeiler, 2002).

During its introduction, lean health required a higher degree of joint production[53] in the region. Decision-making had to be centralised and the customer-choice model was better suited to the kind of scale economy associated with mass production. The new organisation brought internal pricing and thereby provided a new framework for planning budgets (Pfeiler, 2002). The refunding model gives citizens within the region the option of choosing from a range of care providers, including both private and public providers. In 2010 DRG (the case-based reimbursement classification described in Section 5.4) was utilised to reimburse both inpatient and outpatient care (Cederholm, 2010).

[53] The idea of 'joint production' meant that all hospitals had to be part of the same organisation, coordinating their treatment procedures in order to achieve large-scale provision of healthcare services and here through an assumed higher efficiency.

6.3.3 THE ROLE OF EVIDENCE-BASED MEDICINE AND SBU

Even though Lund hospital, just like Uppsala Akademiska, is a research-driven hospital, it still has clear guidelines concerning the use of EBM. Research is an important aspect of everyday activities, which is why physicians are inclined to investigate potential new areas of medicine (Malmberg, 2010a). When assessing new technologies, and bringing new methods into use, one physician at the hospital argues that the time dimension is crucial. The need for new methods is often thought to be immediate; consequently, the need for any new method is present before there are any scientifically proven results. The fast pace of current technological development, in combination with the higher demand for long-term results, is problematic. Obtaining scientific evidence is time-consuming and, during scientific trials, other, further-enhanced technologies can already be developed and be in the pipeline for trial. (Malmberg 2010a; Malmberg, 2010b)

SBU's reports also form part of the everyday work of the physicians in this organisation. At the urology clinic, SBU evaluations are used on a daily basis and recommendations from SBU are important since they are guidelines towards the homogenisation of healthcare quality at the national level. Homogenisation and standardisation are both explicit goals of the hospital (Christensen, 2009; Cederholm, 2010; Malmberg, 2010b).

6.3.4 THE ROLE OF RESEARCH AND EXTERNAL RELATIONSHIPS

Lund hospital receives ALF funding (central funding) to conduct research, which is an important activity for the hospital. It also has renowned competence in many medical areas. The high level of competence is, of course, due to its research activities. The hospital's CEO, Christensen, spoke in 2010 about the palpable competition from Riks Hospitalet in Copenhagen over personnel. Lund University Hospital tries to offer a highly knowledgeable environment, of which research is one important aspect and a way to keep physicians from moving over the strait to Copenhagen (Christensen, 2009).

Contrary to the above statement, however, there are some reports that cast doubt on how research actually functions in the hospital. There are indications pointing to increasing difficulties in conducting research, due to the connections between industry and clinics being more convoluted than before (Bolmsjö, 2009). It has been claimed that there is a decrease in the possibilities of establishing close research collaborations between the hospital and companies. This reduction in research opportunities is due to less organisational

space, slimmed-down production lines and harder pressure on production efficiency. The slimmed-down production, in combination with escalating regulations, has created a more closed healthcare organisation, which has shut the door on collaborations with external partners. There are voices calling attention to the growing demand for research on the one hand, and the lack of platforms for conducting research on the other (Bolmsjö, 2009; Malmberg, 2010a).

There is, then, less money to conduct research; with the hospital's deficit of 102 million SEK in 2005, there is little choice but to cut down on costs. The slimmed-down production lines are seen by some as leaving less room for new projects, but, from a competition point of view, it is important to keep physicians within the county. Research on PLFT was conducted at the urology clinic in Lund and even if much of the clinical research was done in Kalmar, the last dissertation on PLFT treatment was defended in Lund in 2009 (Schelin, 2009).

6.3.5 THE UROLOGY DEPARTMENT AND BPH TREATMENT

In 2010 this department had an outpatient reception but no ward. All inpatient treatments were undertaken at other hospitals within the region, mostly in Malmö. Despite the fact that the department is now part of Malmö University Hospital, this description of the urology department in Lund will be told from the perspective of Lund hospital only. This is only to enable some perspective on the mechanism of technology use, given that the microwave technology started its journey in this using context in the 1990s, when the hospitals in the region were separate organisations.

PRODUCTS

Today, most patients are treated with medication, which is a general trend as shown above. The most common invasive treatment is TURP, which, since 2005 has been performed at a smaller hospital in the region. Regarding PLFT treatment, Lund hospital has a history of periodic microwave use. However, this was not the first hospital in the region to use the TUMT microwave treatment in the early 1990s. Another small hospital within the region, Simrishamn, was the first in the county to acquire microwave equipment with funding from the Social Insurance Office (*Försäkringskassan*). This purchase effectively demonstrates the climate of technology use back in the 1990s – there were high expectations that new technology would help to save money (Malmberg 2010a, Broström 2010a). Lund got its TUMT device shortly after

Simrishamn with the purpose of reducing costs. In Lund, a hundred interventions were performed over a period of two years, after which the department chose to abandon microwave treatment due to poor treatment results.

When ProstaLund launched its new method, PLFT, Lund University Hospital had been an active development partner. Consequently, when clinical studies were settled for PLFT in Uppsala in December 1998, the urology department in Lund sent two of its nurses to Uppsala to be trained in how to use the device properly. After 1998, the method was used sporadically as it was in many other hospitals in Sweden at the time (Malmberg 2010a, Broström 2010a).

The reasons why PLFT was not utilised on any larger scale in Lund were many. The obstacle pointed to most by physicians was the clash between urologists' training to become skilled surgeons and the endeavour to replace their surgical practice with a technological device. Linked to this issue was the lack of opportunity to learn the treatment properly (Malmberg 2010a, Broström 2010a).

FACILITIES

The Urology department at Lund hospital had an outpatient clinic in 2010, but no ward or surgical premises. All TURP surgery was performed in Landskrona – a nearby city in the same region. Despite the urology department's move to Malmö, all TURP surgery is still performed in Landskrona and also in Ystad, although the surgeons performing TURP are the same urologists as the ones employed in Malmö. (Malmberg, 2010a; Broström, 2010a). The physicians are mobile and organised around the facilities, not the other way around.

But, even many years before the merger in 2010, inpatient treatment (TURP) of BPH patients was not done at Lund University Hospital at all. The same patterns occurred as in the case of Uppsala Akademiska, namely the organisational difficulties of embedding PLFT as a treatment that would replace another treatment, which had been outsourced to another local hospital. To treat all patients with the same method has a rationale of scale. Still, there is one important aspect on which the hospitals differ: in Skåne, the same physicians treat patients at different facilities, but physicians in Uppsala perform all their activities at one specific hospital.

ORGANISATION

The strong focus on production by Lund's hospital also has implications for how healthcare is organised and delivered. Nurses and administrative personnel are always located in the same location. Many of the urologists that have

to work at all the hospitals feel their work suffers from switching location, in-between hospitals. Some feel that this stressful situation, i.e., the inability to follow up on their patients and have less control over treatment, sacrifices their everyday work to pure production efficiency (Broström, 2010a; Malmberg, 2010a).

With regard to microwave treatment in the new organisation, it is harder to find time and space for treatments to be performed. One important reason behind this problem is that the flow of patients is more sporadic. There is only one nurse in Lund University Hospital that performs microwave treatment for all patients within the region. To organise time for this treatment is therefore not easy, which is why PLFT treatment is not carried out on a regular basis. The head of the department has even explicitly said that if PLFT were located in the surgical premises, then it probably could be utilised to its full potential, but, then again, such a move would mean that much of its economic benefits over surgery would vanish (Malmberg, 2010a; Broström, 2010a).

We now return to 2001, when the department in Lund changed treatment directions for BPH and decided that all urologists from that point onwards should be able to treat patients with PLFT. Thus, in 2001, the official intention was for PLFT to partly replace surgical treatment. So, what were the underlying reasons for changing the therapeutic standards for BPH treatment in 2001?

First, there was a large pressure for more privatisation of healthcare in Skåne and local politicians discussed microwave technology as an alternative device for private urological care provision. The purpose was to create a private clinic specialised in PLFT treatment and, to finance the project, an equivalent sum of money had to be cut from the urology department's budget. The solution seemed fair from a policy perspective, since the cost of treating patients who (at the time) were treated in Lund University Hospital would now be debited elsewhere, to a private clinic providing microwave treatment for BPH (Malmberg 2010b; Broström 2010b).

Even if such a proposal was hard to digest for a department already under economic pressure, the physicians in charge at the clinic contend that policy directives were not their primary concern for changing treatment routines. Rather, their previous cautious use of PLFT was explained by a lack of scientific evidence. In 2001 instead, they felt they had the opportunity to conduct clinical research while implementing PLFT. A second important argument for implementing PLFT to its full potential was the growing waiting lists for invasive surgery and BPH treatment; Lund hospital had to do something to reduce the waiting time for treatment (Malmberg, 2010a; Broström, 2010a).

To get all urologists at the department using the method turned out to be a harder task than was first imagined. First, this was because PLFT is not just a new technology; there is more to it than that, it is a *method* to learn. The fact that this treatment was a bit more complicated than first comprehended made learning more complex and time-consuming than expected. Another aspect was the urologists' professional development; many of the urologists in Lund were in a professional phase, where they were more into practising open surgery and felt that using microwave treatment would make them stagnate in their professional skills. Consequently, the action plan for clinical testing and full implementation of PLFT came to an end (Malmberg, 2010b).

But, since the department was obliged to treat with microwaves, two nurses, instead of specialist urologists, took care of the PLFT treatment. At the time, it seemed like an optimal solution from many aspects. The two nurses were very skilled in using PLFT, and had had extensive training both from working with the method for many years and also through education in Uppsala at Akademiska. The nurses themselves embraced the task from a professional point of view. Even if their strongest imperative for using PLFT was the benefits to the patients. They also stated it was not hard for them to reschedule their work to make room for PLFT treatment. Between the years 2001-2004, they performed about 100 PLFT treatments each year (Broström, 2010b; Malmberg, 2010b).

Still, in the end, it turned out that making time and space in settled routines for PLFT treatment on a regular basis was easier said than done. PLFT, and the nurses that used it, had to adapt to many diverse issues. First, there was a demand from the physicians' side that one urologist had to be responsible for the treatment, even if that urologist was not actually performing it – someone had to take the professional responsibility and that certainly could not be "done by a nurse". Furthermore, it was not enough that one of the urologists occupied with other work at the department should stand as responsible physician in treatment; there had to be one specific urologist with committed time to PLFT treatment – even if not personally performing it. Accordingly, making time for one nurse to treat with PLFT was one thing, but making time for one nurse *and* one physician was far more complicated (Broström, 2010a; Malmberg, 2010b).

It may seem at first glance that there might be no serious implications in having nurses treating patients instead of physicians doing it[54], however,

[54] The main difference between a nurse and a urologist/physician is that physicians have the overall treatment responsibility for the patient. They also have different kinds of training, where

according to nurse Broström (who, since 2009, has been head of the department), it is of vast significance. If interest is low in the profession, then there is a natural reluctance towards the method, which means patients are seldom referred for PLFT treatment, even if they appear particularly suited for it. The few patients that actually are referred normally have other illnesses or conditions that prevent them from having any surgical interventions. The fact that it is only these patients that are sent for PLFT treatment also diminishes the chance of it becoming an established method. Since these patients already are classified as high-risk, they are either too ill or too old, meaning any treatment would have a higher risk of failure. Still, even if treating only the most ill with PLFT, Broström states that around 80% of patients improved and could be liberated from their catheters as a result (Broström, 2010a; Malmberg, 2010b).

A clear demonstration of the reluctance among physicians is the manner in which PLFT was brought in when there was several months' waiting time for BPH treatment. The waiting time was reduced by using PLFT but, when the waiting time was diminished, physicians argued there was no longer any need for extensive PLFT use. They did, however, continue to treat patients in need of microwave treatment, which amounted to about 54 patients each year until 2010 (Broström, 2010a; Malmberg, 2010a).

RELATIONSHIPS

The Lund department's most crucial relationships are those with other hospitals' facilities and, in some cases, those with other doctors, treating patients from Lund.

Another important relationship for PLFT treatment is of course the long-term collaboration with ProstaLund; the department as a whole has followed the technology from the beginning and brought it into active use several times. PLFT has occasionally been in active use, but its usage has been mostly sporadic.

6.4 KALMAR REGIONAL HOSPITAL

Kalmar regional hospital is a somewhat smaller hospital than the others, still it has been a part of large research projects within urology and in 2009 was the only hospital in Sweden treating 40% of its BPH patients with microwaves (Schelin, 2009).

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urologists have a specific surgical training which potentially can be crucial if anything goes wrong during treatment.

As a smaller hospital providing only a few areas of highly specialised care, the hospital CEO remarks that it does not compete with other hospitals, nor does it sell large quantities of healthcare to other counties. Selling healthcare is not a goal for the organisation. During 2009, the total income for the hospital came to 120 million SEK, out of which 30 million SEK came from sold healthcare. In addition to its income from specialised care is the fact that Kalmar is a small coastal town, located close to a touristic island, which is why in summertime the hospital receives many patients that are simply tourists on vacation. Sold healthcare is largely, therefore, not a result of selling healthcare with neighbouring counties, rather it is an effect of geographical coincidence.

Kalmar Regional Hospital

6.4.1 ORGANISATION

Kalmar Regional Hospital has to work consistently towards becoming more and more efficient but the hospital CEO, Rastad, said in 2010 that it does not experience difficulties in achieving its budgetary goals. Even though external competition is not a factor for this hospital, Rastad puts an emphasis on the value of *internal* competition among all employees in order to achieve greater efficiency. He argues further that the personnel require motivation in order to become more cost-efficient and a competitive environment is one way to achieve motivation. Kalmar Regional Hospital has created a quality compensation system for its employees, and Rastad is convinced that the best way to reach higher efficiency within the organisation is through creating a sense of belonging and high competence. One way to achieve this is by letting each unit have a higher degree of responsibility over its activities and giving incentives to enhance efficiency in production. One example of such an incentive could be that if a unit reached the goal that 80% of patients will not wait more than two hours to receive care, it will get an additional 2% of its established

budget. Each unit has its own responsibility to allocate resources within the frames of the budget and, in this way, can achieve production efficiency (Rastad, 2010).

Generally new technology is introduced into this organisation with a starting point from a treatment and efficiency perspective. The resistance to new technology from the profession is relatively low. However, from a managerial point of view, it is often a matter of balancing the interests of the profession with actual needs and capacity in the production structure. If there is supposedly a general reluctance towards the use of a specific method, management says it is not able to force physicians to use that specific method. Physicians have responsibility over their patients and treatments, and the hospital management will not interfere in their work as long as they adhere to their budget (Rastad, 2010).

6.4.2 THE ECONOMIC ADMINISTRATION AND USE OF REGULATIONS

Politicians set the frames for a general hospital budget, and earmark funding for different areas such as how much of the budget is supposed to be used for facility investment et al. Rastad himself has the executive right to decide over the money spent within these frames.
DRG is used for inpatient care and Kalmar uses both the national list and a local list to price its healthcare (Rastad, 2010).

6.4.3 THE ROLE OF EVIDENCE-BASED MEDICINE AND SBU

The hospital CEO states that SBU reports are of great value to the organisation in ensuring that quality is upheld to a standard equal on par with the rest of the country. SBU evaluations are also considered economically valuable as well as capable of providing guidelines and data to indicate how and when certain methods should be used (Rastad, 2010). However, this view is not necessarily made explicit or shared by the organisation, as one urologist states that the urology clinic does not use SBU reports to decide on treatment methods or to make economic evaluations (Palmqvist, 2010). The decisions on the treatment of patients, at least within the urological specialty, are, to a large extent, based on discussions between colleagues rather than formalised guidelines. In fact, the urology clinic in Kalmar diverges from its peers in terms of how it has arranged its treatment, which is something to which we shall return shortly.

6.4.4 THE ROLE OF RESEARCH AND EXTERNAL RELATIONSHIPS

In a smaller hospital like Kalmar, the possibilities of conducting research are scarce. Physicians with research aspirations most commonly do not apply to work at hospitals like Kalmar. There are some physicians involved in research projects, of course, but when the projects need to be transformed into documented science, the scientific results have to be defended at a medical faculty – a hospital with the right to examine doctoral theses (Schelin, 2010; Rastad, 2010).

Financially speaking, physicians are entitled to spend a percentage of their employment conducting research. There are also cases of physicians acquiring external funds for the same purpose. However, in general, research projects are exceptions rather than the norm at this hospital (Rastad, 2010; Palmqvist, 2010).

Regarding external relationships, smaller hospitals are often dependent on partnering with larger hospitals for access to highly specialised care. Kalmar is rather a buyer than a provider of highly specialised care in most areas. Another important aspect of how Kalmar has organised its BPH treatment also concerns external relationships. This region has one of the highest percentages of BPH patients being treated with PLFT in Sweden, with approximately half of them being treated at a private clinic, while the rest are being treated at the hospital.

6.4.5 THE UROLOGY CLINIC AND BPH TREATMENT

At Kalmar Regional Hospital, the field of urology does not have its own department, but is a clinic within the larger surgical department. At small hospitals, this is a common way to organise urology, since it is a surgical specialty. Six urologists are employed at the clinic as well as a handful of nurses. Generally, they have about 3,600 visits a year, out of which ca. 450 are patients with BPH (Palmqvist, 2010; Wagrell, 2010).

PRODUCTS

In Kalmar, they have the same general BPH treatment setup as is found in other hospitals, i.e., active treatment has decreased in recent years in favour of medication. Still, the department treats around 140 patients a year with active treatment (90 TURP and 50 PLFT). Four out of six urologists are able to operate the PLFT device effectively, but rather than leaving it to a physician

to make a decision about whether to treat his or her own patient with PLFT or TURP, at Kalmar there is a common diagnostic ground and seemingly non-formalised criteria for what treatment patients are suited to. Palmqvist explains that the assessment of treatment is closely interlinked with both the size and shape of the prostate, as well as the more common diagnosis features such as age and general condition. This is the first clinic to emphasise a range of explicit diagnosis criteria also based on physiological prerequisites of the prostate and how such conditions affect treatment options. These are not uncommon criteria. Also, at other hospitals, e.g., the aforementioned one in Lund, urologists use at least the size of the prostate as an indicator for suitable treatment options. However, in Kalmar, urologists put a special focus on the physiological shape and placement in relation to urethra and translate their knowledge of these combinations into general active treatment options. Based on these specific treatment criteria, the urology clinic in Kalmar performed 700 microwave treatments between 2001 and 2010 (Palmqvist, 2010).

FACILITIES

As the clinic is part of a larger surgical department, it has access to surgical premises but, even at a smaller hospital like this, central surgery is a bottleneck. The notorious bottleneck was the core argument when introducing PLFT in 2001, which was brought into use to unburden the surgical department. In 2010, minor surgery is performed in a nearby city, Oskarshamn, where there is a subunit to the urology clinic in Kalmar, named Karl-Oskar (Palmqvist, 2010).

ORGANISATION

To understand the development of PLFT at this hospital, we must start from the beginning and look at how things evolved at the hospital in the early 1990s. Kalmar had a urologist, the aforementioned Schelin, who was the first urologist to get involved in the microwave development project in Kalmar. The combination of his friendship with Bolmsjö and pressure from STU (See Chapter 4.4) motivated him, despite his scepticism, to begin the temperature study in Kalmar in the mid-1990s. Since this development, Schelin has been a part of this ongoing project and has developed catheters and other technical equipment in order to make the technology more suited to treatment needs (Schelin, 2009; Bolmsjö, 2005; Wagrell, 2010; Palmqvist, 2010).

Schelin was, furthermore, head of the urology clinic at Kalmar hospital during the 1990s, but resigned to open his own practice in 1996, when he had a 'fall out' with the hospital board. He criticised what he saw as a poor organisation at the hospital and did not feel he got any response to his complaints (Schelin, 2009). Starting his own clinic did, however, not stop him from continuing with his research and development of microwave treatment. Being a renowned urologist, many patients with BPH troubles were sent to him by the hospital's urology clinic to be treated with microwaves (Schelin, 2009). Kalmar hospital eventually decided that all patients suited to PLFT treatment should have the possibility to receive it. The difference in Kalmar, from the other hospitals discussed here above is that a large share of the PLFT treatments are outsourced by the public hospital organisation to the private clinic of Schelin (Schelin, 2009; Palmqvist, 2010).

However, even if Schelin had left the hospital clinic in the 1990s, he had left a training urologist there with a construction project. The project had made an impression on the other urologists. As the project moved on over the first half of the decade, the personnel at the clinic gained a substantial amount of knowledge of microwave treatment. Since the hospital clinic was small and had no parallel research projects, all personnel could follow the project closely and they had the opportunity to develop a deep understanding of how the technology worked. It seems urologists in Kalmar are grounded in a deeper understanding of the technology that has been translated into explicit diagnostics, that is, how the method affects patients and which specific prostates are suited to microwave treatment, rather than what kinds of patients are suited to PLFT treatment (Palmqvist, 2010). But they have also kept up to date with the scientific development of the device through the company ProstaLund, through their relationship to Schelin and through scientific documentation in the form of publications (Palmqvist, 2010).

Whether this knowledge was first put forth by Schelin 15 years ago, or emerged successively during the development of the technology is more or less impossible to know. Regardless, this clinic has a different understanding of the methodology and a different way of diagnosing patients than other hospitals. However, Kalmar did have difficulties in finding the time and space in which PLFT could be performed without disturbing other activities. During the first years after its introduction, PLFT was performed in the ward but it was not an optimal solution for urologists; when they reorganised treatment of PLFT to the outpatient clinic, it became easier to reschedule. Besides, a nurse became responsible for all follow-up appointments and took responsibility for creating a waiting list for PLFT patients. When the list started to

lengthen, the nurse made sure one of the urologists was able to dedicate a whole day to PLFT treatment (Palmqvist, 2010).

A recurrent theme when discussing new methods with physicians is the matter of *hospital size*. Physicians' tasks are dependent on the size of the hospital. At smaller hospitals, physicians have to treat a broad spectrum of patients compared to physicians at larger hospitals. Everyday work tasks are rather diverse. At a large hospital, physicians are able to develop advanced specialised skills to a higher degree. A urologist at a smaller hospital treats only a few BPH patients a month while, at a larger hospital, physicians are able to develop their skills in various BPH treatment methods. It can be assumed that a urologist that has performed 500 PLFT operations and probably has less difficulty in achieving high-quality results than a urologist performing sparse operations. Kalmar is, however, a small hospital with only six urologists, but it has still succeeded in achieving results with PLFT treatment comparable with those of surgery.

RELATIONSHIPS

At the Kalmar urology clinic, it is possible to directly point to the importance of relationships and how knowledge gained through these relationships got embedded into a structure and stayed there. Many of the urologists at this clinic are former colleagues of Schelin, who in turn had a personal friendship with Bolmsjö, which is one reason why the development took place in Kalmar. When Schelin chose to leave the clinic, just after initiating the development project with ProstaLund, he left a training urologist with a new project. Against the odds, the project was carried out, even if the initiator and supervisor of the project had left. During development, it seems that all urologists at the clinic gained a technological knowledge that they have been able to translate further into the more advanced technology of PLFT and then into very specific and complex diagnostic criteria. The prevailing consensus among urologists regarding which patients should be treated with PLFT and which should not, seemed self-evident at this clinic. Such understanding can only be due to their extensive experience of the method, which is something the urologists have gained through close cooperation with developers of the method over a longer period of time.

6.5 CONCLUDING REMARKS

The use of microwave technology in BPH treatment has varied among the presented contexts: what is seemingly so promising in one specific context, loses its value in another. The story points to how technology tends to develop and lose momentum over time. Some contexts helped the technology to thrive and develop, while others did not support its becoming embedded.

What is interesting in these diverse user-contexts is that the technology had differing functions depending on how the hospitals were organised, the size of the counties, the research setup, etc. Another interesting point that needs to be discussed further, which also points to the strength of users, is the importance of understanding the different ways in which the new technology is adopted in public healthcare. The next section provides an analysis and results of the study and points to the central drivers and hindrances in the innovation process of TUMT/PLFT in the different settings of development, production and use.

PART III. ANALYSIS & RESULTS

This section comprises four chapters, 7-10. The first two chapters, 7 and 8 presents the analysis. These chapters discuss the empirical findings, which are organised around the three empirical settings of developing, producing and using. The developing and producing settings are discussed in Chapter 7 and the analysis of the using setting is presented in Chapter 8. The analysis of the settings rest on the theoretical approach presented in Chapter 2. Each setting will thus be analysed separately, identifying the most crucial interfaces and the key drivers and hindrances in the innovation process. Chapter 9 presents the results of this study and Chapter 10 provides concluding remarks, contributions and some considerations for further research.

7. THE DEVELOPING AND PRODUCING SETTINGS

The following sections will focus on the most salient interfaces in the developing and producing settings. The interfaces are categorised into the different resource types represented in the 4R model. In this analysis, they are abbreviated; products (P), facilities (F), organisational units (OU) and business relationships (BR). For example, interfaces between organisational units and products will be referred to as (OU- P), or any combination of the four resources types.

7.1 THE DEVELOPING SETTING– PUBLIC–PRIVATE INTERACTION

This section analyses the specific aspects that drove or hindered the development of TUMT, with starting point in the most salient resource interfaces that has been identified through the 4R model. The section is divided into three main parts with the following topics;

i) The NPM reform triggers and leaves visible imprints in the development of both TUMT and PLFT (7.1.1)

ii) Public funding was crucial to the development of TUMT (7.1.2)

iii) Public healthcare was a pivotal platform both in the *technological* and *scientific* development of TUMT (7.1.3)

7.1.1 THE VISIBLE IMPRINTS OF THE NPM REFORM IN PRACTICE IN THE DEVELOPMENT OF BOTH TUMT AND PLFT

Following the development of the microwave device from the very start, we see that it took many years and many different contexts in different countries just to develop and test diverse versions of the very first microwave technology. In Sweden, *one* specific person (M. Bolmsjö) had been partially involved in the international technological development of TUMT that had taken place in Israel, Italy, France, the Netherlands and the USA. Thus, the idea was not *born* within the Swedish system. Still, the knowledge of microwave technology in the treatment of BPH was gathered in that one person and his small business in southern Sweden. Yet, the initiative to develop a Swedish TUMT device did not awake from this small business: it was instead a *user-driven* development that took place between this small Swedish technology consultancy firm (Lund Instruments) and Swedish public healthcare, Örebro University Hospital.

To develop new medical technologies has never been a simple task, not for public healthcare and not for companies. Even before NPM principles entered the public healthcare system, it was ridden with high complexity. However, in practice, NPM brought one decisive change: a larger emphasis in the whole healthcare system on *financial* aspects and accountability of smaller, organisational units of the level of single hospital clinics. Before the systemic change, physicians' call to develop new treatment methods were at large based on the needs among patients, or perhaps even a call or curiosity to contribute to the progress of medical science as such. However, NPM introduced an outspoken *financial spur* at the level of the single clinics where first line managers were held financially accountable for the outcome of their organisational unit's activities. It was foremost these new financial responsibilities that triggered the first development of TUMT. Here below are presented four of the most salient interfaces in the early development of TUMT.

- ***Lund instruments–Italian med-tech supplier*** (OU–OU):
  This business relationship emerged in the 1980s and is a significant resource to the Swedish development of TUMT that would take place years later. It meant that Bolmsjö, the man behind the business unit Lund Instruments gained further knowledge about microwave treatment for BPH troubles and became embedded further into an international network of other medical technicians and companies with an interest in microwave treatment. His knowledge and interconnection

to an international network should turn out to be especially valuable years later in the Swedish context.

- ***NPM accounting–Örebro (USÖ) urology department*** (OU–OU):
  It was the new financial situation at the department USÖ that triggered the early development of TUMT. In the turn of a hand, the chief urologist at the USÖ department was held accountable not only for treatment results but also for the financial outcome of his department. He was more or less constrained to search for more cost-efficient methods. Furthermore, the largest savings could be made in high-cost items and widespread diseases, such as BPH. This specific chief urologist acted upon new financial incentives and control tools, searched for a more cost-efficient treatment method and eventually found a partner outside the healthcare context, as described in the next interface.

- ***USÖ urology department–ProstaLund*** (OU–OU):
  This is the first private/public relationship in our innovation process and it resulted in the development of the first Swedish TUMT device. As discussed, the introduction of NPM principles triggered the establishment of this crucial interface. The development of a new device required both specific technological knowledge and facilities adapted to TUMT development. Neither the specific technical knowledge nor the facilities were available within Örebro's own healthcare context, but were made available by the private organisation ProstaLund.

- ***TUMT–Treatment method*** (F–OU):
  The development of the more advanced version of TUMT, known as PLFT, was initiated because the first device was not enough technically sophisticated. The treatment method had to be individually adjustable so to fulfil individual needs among patients.

- ***PLFT device– Kalmar urology clinic*** (F–OU):
  In the development of PLFT, it was the *logic* behind *provision of healthcare services* that mainly guided the development. The financial imperative became explicit through 'one procedure thinking', which was a general strive for most hospital organisations at the time, hence to not have more than one treatment option for each disease. In the case of PLFT, the surgical treatment TURP was the comparative treatment procedure directing the development of PLFT. PLFT had to

replace surgery and thus be as efficient as surgery. From ProstaLund's point of view, it was a feasible starting point; a method as efficient as the existing gold standard procedure, TURP, which enhanced the chances for widespread use, i.e., commercialisation.

From these interfaces, a few drivers and a hindrance have been identified, they are presented in table 2 here below.

DRIVERS AND A HINDRANCE IN THE INITIAL DEVELOPMENT OF TUMT AND PLFT

DRIVERS	HINDRANCE
The broad international interactions of the consultancy firm – The fact that Sweden had one person/consultancy firm that had been involved in the international development of this microwave technology enabled the initiation of the Swedish TUMT development. The crucial knowledge provided by a small private business (Lund Instruments) and a middle-sized, non-academic, public hospital, USÖ. Bolmsjö's prior business in an international context and his knowledge about the technological development and clinical testing that had taken place in an international context was thus crucial to the development of the first Swedish TUMT device.	***TUMT technology is insufficient in the treatment of BPH*** – The TUMT technology was a rather 'simple' technology that provided the same treatment procedure for all patients, independent of prostate size or degree of prostate trouble.
Regulatory changes create financial incentives and trigger the development of TUMT– The Swedish authorities' organisational changes, manifested through NPM, triggered the initiation of this innovation process. The systemic change held clinic units financially accountable for undertaken activities, which triggered the chief	

urologist from USÖ to search for new and more cost-efficient methods.	
NPM-inspired production logic creates imprints in the development of PLFT– The systemic change pushed the development of PLFT to become a more refined and individually adjustable treatment technology. Withstanding a 'production logic' in healthcare that favoured one treatment procedure for each disease - the main objective with the PLFT development was to make it compatible with surgery, thus paving the way for a more economic/efficient main procedure in the treatment of BPH.	
Public-private interaction enables the development of TUMT–The fact that the department at USÖ was too small an organisational unit to unilaterally carry an investment in a TUMT-device – made available by international producers – triggered the development. USÖ did not have the facilities or competencies to develop a device alone, however one of the hospital's medical technicians knew that one person in Lund had the experience and knowledge they needed to construct a microwave device in the treatment of BPH, i.e., Lund Instruments.	

Table 2. The Drivers and Hindrance identified in the initial development of TUMT and PLFT

7.1.2 THE CRUCIAL SUPPORT OF PUBLIC FUNDING IN THE FURTHER DEVELOPMENT OF TUMT AND PLFT

The development of TUMT was dependent on public funding. The case shows how public funding has contributed to its affecting not only on the resources to which it is targeted, but also the interlinked resources.

- **Technology procurement – Örebro urology department & ProstaLund** (OU–BR):
  The TUMT project conducted within the business relationship between ProstaLund and Örebro's urology department received funding through technology procurement. At the time, ProstaLund was a small consultancy firm without any of its own financial capacity to invest in a development project. Likewise, the urology department at USÖ did not have any central funding for conducting clinical research. However, the procurement organisation did not interfere in the department's choice of a collaborating partner. Indeed, the project and hence, the relationship between ProstaLund and the USÖ urology department, was funded.

- **Kalmar County–The urology clinic at Kalmar Hospital** (OU–OU)):
  The county of Kalmar funded the development project of TUMT/PLFT with the intention of strengthening the use of new and efficient methods at the hospital. Without this support, it would have been difficult for the project to proceed at all.

- **NUTEK–ProstaLund** (OU–OU):
  The second round of development, which resulted in the development of the PLFT device, was funded by NUTEK, which more or less 'pushed' ProstaLund to continue their business and continue with a second round of development instead of going out of business. Nevertheless, ProstaLund had to find a development partner in a public healthcare setting. If the urology clinic in Kalmar had not been able to mobilise the resources to engage in this development (see previous interface), the funding from NUTEK would not have made any difference in the innovation processes as a whole.

Public financial support was important throughout the development of the microwave device and it provides a few drivers to the innovation process of *financial* character. The innovation process and the resources that had been co-developed in the public–private interface relied upon a variety of mostly public financial support. Private funding would become important later on, during the mass production of the PLFT device. The drivers are presented in Table 3.

DRIVERS FROM PUBLIC FINANCIAL SUPPORT IN THE DEVELOPMENT OF TUMT AND PLFT

DRIVERS
Public financial support from procurement organisation – Public financial support that was not earmarked to any specific collaborating partner was crucial to the innovation process. A very small private producer was able to become a partner of public healthcare due to this kind of structural financial support. The fact that the relationship could be established without any interference from authorities enabled a very small private consultant to establish a co-development project with such a large actor as public healthcare. At the very beginning of this innovation process, ProstaLund was an extremely small consultancy firm, with only one employee. Both the department at USÖ and ProstaLund consequently had to mobilise resources, especially financial ones, in order for this development to take place at all.
Public financial support from The County of Kalmar – Regional hospitals like Kalmar, which do not have their own funding to conduct research, are entirely dependent on public financial support in order to conduct any kind of development/research activities. The technological development in Kalmar was entirely reliant on county-level financial support. This was not funding earmarked for clinical research purposes, but rather an investment in technological development, made by the county.
Public financial support from NUTEK – The funding from NUTEK and their engagement in the further development of TUMT into PLFT functioned as a 'push' into the second round of technological development.

Table 3. Drivers from public financial support in the development of TUMT and PLFT

7.1.3 PUBLIC HEALTHCARE – A PIVOTAL PLATFORM BOTH IN THE TECHNOLOGICAL AND THE SCIENTIFIC DEVELOPMENT OF TUMT AND PLFT

Medical technology innovation is involved with both a practice-based development that is close to an industrial/technological development and scientific development, which is closely related to an academic context. This implies that a new med-tech solution not only has to be technically developed and related to the 'healthcare provision processes,' but it also goes through a scientifically oriented development process. These two aspects of development are indeed overlapping: results from technological development are documented, but not made available through scientific publications since they are

not considered 'scientific' in the proper sense. Hence, the results have to be considered and scrutinised within an academic context to be made available to others in the academic community.

There are also diverging incentives with regard to the imperatives to engage in either technological or scientific development. In the case of TUMT and PLFT, the involved hospital departments have contributed in different ways to the project's development; some, to a larger extent, have contributed to its industrial/technical development and others to the scientific development.

In this regard, the case points to an important division of activities between hospitals as to why this section provides perhaps more detailed interfaces than the other sections. It is a way to show that the actual development of new devices takes different forms. At research-driven hospitals, e.g., Uppsala Akademiska Hospital, the scientific results have a value per se and these hospitals also have stable funding to conduct clinical research. Smaller regional hospitals also undertake development of new devices, but their perspective on the value of the new solution differs from research-driven hospitals. At a small hospital, the value of engaging in the development of TUMT and PLFT development is related to the devices' potential effects in practice, i.e., how the new device performs, as a technical tool, in relation to established healthcare production processes. Therefore, below here a set of key resource interfaces will be identified, first for the technological development and then for the scientific development of TUMT and PLFT.

TECHNOLOGICAL DEVELOPMENT: *CLINICAL TRIALS IN CLOSE INTERACTION BETWEEN INDUSTRY AND MEDICAL PRACTICE*

The technical development of the TUMT and PLFT device took place at one middle-sized and one smaller hospital: USÖ and Kalmar. To engage in a development project of the size of TUMT implied a considerable investment. The trigger to engage in the development of TUMT and PLFT was closely related to the device's potential to contribute to an enhanced efficiency in healthcare provision of services, be it diminishing costs or enhancing treatment results. Furthermore, these two clinics were dependent on public local 'ad-hoc' funding to finance the development projects since they both lacked their own guaranteed funding to engage in development projects.

Another pivotal aspect of the technological development was that the resources provided in the focal relationships with the private developer were not sufficient for the innovation process to proceed. Other sources were needed to

overcome unexpected problems and to test new solutions along the way. The emergence of particular technological issues during the technical development suggests the following interfaces as being especially important:

- **TUMT–USÖ urology department** (F–OU):
  The project conducted at USÖ was 'close to practice' and concerned with technical development. The goal with this development was to *substitute* the established surgical method TURP in the overall treatment of BPH at this department. Even if there was initially an agreement that the urology department would continue to conduct clinical studies, which they in the end never did; scientific development was not the prime objective with this project. The intention was to create a device that could function as a tool to rationalise the treatment of BPH and thus lower the overall costs at the USÖ urology department. To contribute to 'healthcare production' rather than science was the main purpose of the project.

- **USÖ urology department–ProstaLund** (OU–OU) :
  This relationship is a pivotal resource per se in the innovation process of TUMT. The fact that these two organisational units were able to develop a thick relationship and openly share and develop joint resources in the public/private interface was crucial to the development of the TUMT device. It is remarkable that the most suitable competencies were found in a small one-man consultancy firm and that this very small business had the capability to establish a relationship with a far larger organisation in public healthcare, like USÖ. The establishment of this interface between private and public was not formalised, but built on an understanding of the competencies distributed between the direct users of the TUMT device, the USÖ urologists who had knowledge of how to treat BPH and the man behind the company - an engineer capable of building a TUMT machine to conduct the treatment.

- **TUMT–New knowledge at Kalmar Hospital** (F-OU):
  At the urology department in Kalmar, previous treatment results indicated the intra-prostatic temperature to be a decisive factor to decide upon individual length of treatment and strength of radiation. After using temporary devices, i.e., sensors placed in the prostate during treatment, this hypothesis could be confirmed by the new test results. The main technological challenge was how to measure the intra-prostatic temperature during microwave treatment, since microwaves create magnetic fields that complicate the measurement of temperature.

- **The needle-catheter–Kalmar urology clinic** (P–OU):
  The new component product was developed during the above testing. Integrating a small thermometer, in the shape of a needle, into the catheter, solved the problem of measuring the intra-prostatic temperature. The solution was both a medical and a technological solution and resulted from a long involvement of Kalmar's clinic in this development.

- **The geology department at Lund University–ProstaLund** (OU–OU):
  New findings in the field of geology enabled further development of technological features in the TUMT device. The new knowledge from Lund University could solve the problem of calculating tissue destruction during treatment. Further, this knowledge could be integrated and tested quite fast due to the close interaction between ProstaLund and the clinic in Kalmar and the fact that the founder of the company was involved in other collaborations at Lund University.

- **The colour-doppler–TUMT** (F–F):
  In order to develop the technology and make it more precise and adjustable to individual patient needs, the team (urologists at the Kalmar hospital and ProstaLund) had to use ultrasound diagnosis. Coupling that to a Colour Doppler could in turn generate a better understanding of the process of tissue destruction during treatment. Since it was a temporary need and financial means were scarce the Kalmar clinic could arrange a temporary contract to 'borrow' a machine from a private company.

From the six interfaces discussed above a few drivers to the innovation process, were identified, discussed in table 4 here below.

DRIVERS IN THE TECHNOLOGICAL DEVELOPMENT OF TUMT AND PLFT

DRIVERS
Relationships allowed direct interaction between ProstaLund and public healthcare – The possibility to build a profound relationship, and hence have an *open interaction* between private and public organisations, facilitated the technical development of TUMT. The ability to both share and create joint resources was crucial to this kind of development. Since development is iterative in its character, going back and forth between clinical testing and technological development, a close collaboration between the users in healthcare and ProstaLund was necessary.
Indirect interactions – ProstaLund was embedded into a network of business actors and scientific settings other than medicine, which provided an opportunity to bring in necessary social and material resources outside the focal relationship between ProstaLund and the various urology departments. The interaction patterns observed in the development of PLFT, to a large extent, corresponds to the basic functions of how development processes are undertaken in the business landscape. The ability to create informal relationships, long-term or short-term ones, and to involve more than one organisation to contribute with knowledge and other resources when necessary is held to be a pivotal mechanism in the iterative patterns that are common in many other innovation processes.
Financial use in healthcare practice – Both Kalmar and USÖ were involved in 'technological' development, driven by financial incentives to enhance the efficiency and thus create savings in healthcare practice.

Table 4. Drivers in the technological development of TUMT and PLFT

When the technological development had reached a state where the device was rather "settled" and perhaps more concerned with 'fine tuning' of methodological details, the development took a new turn towards a *scientifically* oriented development of the new PLFT device.

SCIENTIFIC DEVELOPMENT*: CLINICAL TRIALS BETWEEN MEDICAL PRACTICE AND THE SCIENTIFIC COMMUNITY*

Research-oriented Swedish hospitals have another rationale for engaging in the development of new methods than smaller regional hospitals. At a university hospital, development projects can be approved because of their expected scientific/academic relevance rather than a potential financial contribution to provision of healthcare service. Simply put, for a small hospital, development is an investment with outspoken financial overtones, whereas a research-driven hospital has the leeway to invest in a development project purely for academic purposes. Therefore, the following interfaces stand out as particularly relevant for the scientific development of PLFT:

- **PLFT–Uppsala Akademiska urology department** (Akademiska) (F–OU):
  This large research-driven department did not have to make any larger investments in the PLFT project. Instead, the research project per se added value to Akademiska's urology department. It could potentially generate publications, valuable scientific results and additional research funding. Thus, the PLFT-project created direct value for Akademiska, without the need to make any initial investments in the technological development of the device, nor had any outspoken interest or commitment to bring the method into regular use. The largest investments in the technology had already been made by the smaller hospital departments (USÖ and Kalmar), who had struggled with the drudgery of technological development, construction and initial clinical testing.

- **ProstaLund–Uppsala Akademiska urology department** (Akademiska)(OU–OU):
  This was a weak relationship as the interaction between ProstaLund and Uppsala Akademiska cannot be compared to the previous interactions the company had with Kalmar and USÖ. When ProstaLund more or less had anchored the technological development of the device in Kalmar they had to create a new interface towards Akademiska in order to obtain academic recognition for their new device. This development project was closer to an academic setting, concerned with developing the methodology and a scientific verification of the device and its method. This development required 'objectivity' so as to minimise commercial bias. The PLFT research project was actually criticised by its own department at Akademiska: some opponents were

concerned by the high involvement of the company in previous development. Thus, the relationship between Akademiska and ProstaLund also had to be kept weak as a way to maintain the objectivity of the scientific results.

- **PLFT–Uppsala Akademiska urology department** (F–OU):
  The scientific production taking place at Akademiska was a doctoral thesis on the PLFT method comprising a set of scientifically anchored methods and knowledge of how to use the new device.

- **PLFT–Growing scientific knowledge on microwave treatment** (F–OU):
  Similar clinical studies were undertaken in other medical academic contexts in Sweden, around the same point in time. Uppsala Akademiska could then benefit from the PLFT project as such since it was 'in line' with other academic settings at the time and could contribute to and participate in the academic discussion on the treatment of BPH.

A couple of drivers were identified from the four interfaces outlined above. The drivers concern the significance of scientific evaluation in relation to the med-tech innovation process. This is connected to the fact that before new methods can be brought into in regular use in public healthcare they have to be evaluated on a scientific basis.

DRIVERS
PLFT gains scientific relevance when embedded into an academic setting – interestingly, the weaker private–public interface, that is, between ProstaLund and an academic setting, made it easier to embed PLFT into an academic setting. Since the previous strong interconnections to ProstaLund were considered 'malpractice' within the scientific community, the PLFT device gained academic relevance from the weaker interconnection to the company.
Scientific evaluation enhances the chances for PLFT to become embedded at a systemic level – The academic development is significant to the innovation process as it can aid the new technology to become embedded at a systemic level in the future. Central authorities need a significant amount of data in order to conduct health economic assessments. Data deriving from a non-scientific environment commonly has less significance as a basis for health economic assessments. The scientific labelling of the development is held to be important in this respect.

Table 5. Drivers in the scientific development of PLFT

7.1.4 CONCLUDING COMMENTS ON THE DEVELOPING SETTING

Here in Section, 7.1, numerous drivers and one hindrance have been identified to the innovation process in the developing setting. This setting provided foremost drivers to the innovation process. Taken all together, the drivers can be aggregated into different overarching *types* of *drivers* in the development of TUMT and PLFT. They are presented in table 6 here below.

Furthermore, the case points out an important division of development activities. Scientific and technological development are perhaps not perfectly separable, but for the users the two types of development entail different incentives: to engage in *technological* development corresponds to an 'in practice' perspective, driven by financial incentives. Whereas the University hospitals have a commission to conduct research. To engage in the clinical trials of a device which is already constructed creates academic value for the department, without necessarily contributing to improving healthcare provision of services at the very same department. The case then shows that the more the development of the PLFT device moves towards an academic setting, the less deep the private–public interface becomes. The academic logic provides other incentives to engage in development (e.g., publications) than the technological/industrial development, which is closely related to medical practice and the provision of healthcare services.

When the new solution, PLFT emerged and attracted much attention is evaluated in retrospect, it could easily be considered as an 'innovation' from Uppsala University, where the first thesis on the new method was defended and its scientific merits were assessed. However, with the whole journey at hand, we know that Uppsala Akademiska hospital was the 'end station' of a very long development process that had started in an international context where the core technology had been developed over many years in different countries. But also in Sweden, the device had undergone an encompassing technological development at two smaller hospitals prior to Uppsala Akademiska.

OVERARCHING CATEGORIES OF THE DIFFERENT DRIVERS IN THE DEVELOPING SETTING	
Multiple sources of resources	Social and material resources deriving from an international network of med-tech suppliers and researchers were made available to Swedish healthcare users through a small one- man consultancy firm. In the development of the second generation, the PLFT-device, the network of the private firm contributed, once again, crucial resources in the technological development of the PLFT device.
Organisational interaction	The possibility to have close interaction in the private-public interface made it possible to take advantage of the multiple sources of knowledge and technical and financial resources that contributed to the advancements in development.
Regulatory	The regulatory changes brought about by NPM stimulated the development of TUMT in that it triggered the search for more efficient treatment methods. The new financial spur also made imprints in the further development of PLFT and the aim of this particular project.
Financial	Dedicated financial support (either from innovation support agencies like NUTEK or at a county level) was crucial during the technological development since the organisations involved did not have sufficient capital to follow through with development by themselves.
Scientific	The scientific development is important for a new method to become embedded in medical science. Scientific evaluation can also aid the technology in becoming widely accepted as a regular treatment method in the larger healthcare system.

Table 6. Categories of Drivers in the developing setting of TUMT and PLFT

7.2 THE PRODUCING SETTING - MOBILISING RESOURCES TO EMBED PLFT INTO A PRODUCTION NETWORK

The producing setting foremost concerns ProstaLund's struggle to mobilise resources in order to embed their PLFT device into a production network, thus establishing regular production of PLFT into a feasible cost. The PLFT technology had to become embedded into a larger production network, something that in turn demanded further investments for the company ProstaLund.
In the development of the first TUMT device, the company was 'transformed' from Lund Instruments to ProstaLund, a company that should be capable of producing the new device. The first TUMT device was embedded into an already established, smaller, network of producers and ProstaLund employed new personnel in order to handle the production of TUMT and new customers. Still, most of the production of the first TUMT device was handled in-house and was based on rather standardised components from suppliers.
However, after the second round of development, resulting in the PLFT device, ProstaLund started to prepare for large-scale production. With the new, more complex, PLFT device, ProstaLund had to outsource a larger part of the production in order to keep costs down. The scaling of the production of PLFT was more expensive and demanded larger efforts than the previous version TUMT technology. Consequently, ProstaLund had to become embedded into a new kind of production network, with sub-suppliers able to handle large-scale production of the complex device and their central business partners in the end because of Medical Rubber and PartnerTech.

- **ProstaLund–Medical Rubber** (OU–OU)**:**
  This interface was crucial in order to achieve large-scale production of the needle catheter. The first seven catheters, which had been utilised in the clinical trials at Kalmar Regional hospital, had been constructed in the small workshop in Lund. However, it was not possible and far too expensive to create any large-scale production in ProstaLund's existing facilities. The development of a new production process for the needle catheter could not have been realised without Medical Rubber's extensive knowledge in producing medical devices.

- **The needle catheter–Medical Rubber production facilities** (P–F):
  Medical Rubber and ProstaLund had to make new investments in order to embed the needle catheter into existing production structures. These investments were expensive and ProstaLund had to apply for further financial support.

- **NUTEK–ProstaLund** (OU–OU):
  NUTEK funded the production process development of the needle-catheter. Meanwhile, NUTEK also acted as a gateway to a network of private venture capitalists. A condition for ProstaLund to receive the funding from NUTEK was co-funding from private actors.

- **Venture Capital–ProstaLund** (OU–OU):
  Venture capitalists provided further financial support but also new competencies to ProstaLund. A new CEO and a new organisation was developed during this period with the aim to commercialise the PLFT device in a larger scale outside Sweden.

From these interfaces a few drivers and hindrances are identified, which are presented in Table 7 here below.

DRIVERS AND HINDRANCES TO COMMERCIAL PRODUCTION OF THE PLFT DEVICE

DRIVERS	HINDRANCES
New business relationships– The new business partners in the production network were crucial and willing to enable commercial production of the PLFT device. Without the new partners' knowledge in production processes and their capacity to produce complex technological components for medical devices on a large scale, ProstaLund would have major problems manufacturing their device.	***Increased technological complexity–*** The PLFT device was more technically advanced by comparison to the TUMT device, which was a hindrance in its production. New technical features required new production solutions that were both expensive and complex to establish.
Growth of the internal organisation – The fast growth of ProstaLund's internal organisation was driven by the new owners, the venture capitalists. The fact that the company grew with their investment made it easier to embed its manufacturing into the new production structure of other large suppliers. New business relationships to PartnerTech and Medical Rubber, with long experience and high expertise enabled production.	***Increased costs to embed PLFT into production*** – With increased technological complexity comes higher expenses. To embed a new complex technology into a production network thus required larger adaptations between the new and the already established resources in the production network and thus larger investments.
Public and Private funding (VC)– Both public and venture capital were central drivers that enabled embedding of PLFT into a new production structure, where parts of the more complex device could be produced at a feasible cost.	

Table 7. Drivers and Hindrances to commercial production of PLFT

7.2.1 CONCLUDING COMMENTS ON THE PRODUCING SETTING

The drivers were new business relationships, which allowed ProstaLund to embed PLFT into a production network enabling commercial production of the PLFT device. Nevertheless, to embed PLFT into production implied substantial investments and mobilisation of external capital, from public funding as well as venture capital. Something that in turn brought encompassing internal changes for ProstaLund.

The major hindrance in the producing setting was the *production complexities* caused by the fact that the further developed PLFT technology was complex and difficult to produce at a large scale at a viable price. To overcome these difficulties, the company enrolled new capital, which brought changes that enabled the commercial production of PLFT,

The question is then: What motivated these large efforts and investments to embed the PLFT device into large-scale production?

As discussed earlier in the theoretical chapter, the interconnection between the developing setting and producing/using settings is central, yet difficult to achieve. Companies base their decisions to scale up their production on a presumed need among the users. The previous interfaces with healthcare users reviewed in the developing setting can explain the reasons behind the investments to embed PLFT into production. First of all, ProstaLund made substantial investments in developing their device and aspired return on investment. Especially the earlier interactions with healthcare practice, namely urologists, gave ProstaLund profound knowledge about their user's needs.

ProstaLund made a range of profound changes as the company and its technology became embedded into a partly new production network. As venture capitalists assigned a new 'professional' CEO to the company, ProstaLund changed its internal organisation and strategic goals. At the same time, the device underwent clinical trials in an academic context at Uppsala Akademiska Hospital. These changed conditions, from both healthcare organisations and ProstaLund, put new constraints on the public/private relationship. The informal projects and close interactions that before had characterised the company's relationship with healthcare (USÖ and Kalmar) now became more formalised, detached and less profound with Uppsala Akademiska Hospital.

Despite the long co-development of the device and close private-public interactions in the healthcare system, it was cumbersome to handle the new formalized terms of the user interface from the producer's perspective. At the point in time when ProstaLund chose to scale up production, that decision was

mainly based on knowledge of the needs in *clinical practice* as they had emerged from close interaction with USÖ and Kalmar hospital (see section 7.2). What ProstaLund instead did not consider in their decision to scale up were the requirements at a systemic level. Nevertheless, to achieve *wide-spread* use in the healthcare system also requires embedding at a systemic level. The next chapter will analyse the embedding of the TUMT/PLFT device into the using setting.

8. THE USING SETTING: FROM RECOGNISING CONTEXT DEPENDENCE TO STANDARDISATION

This chapter analyses the Swedish using setting and the specific drivers and hindrances to embed TUMT and PLFT into regular use in public healthcare. The chapter is divided into two main parts:

The first part, 8.1, provides a *general* perspective of embedding TUMT/PLFT into public healthcare and includes both the systemic and specific levels, thus considering use from a general perspective and the *potential value* of using a microwave device from a given physician's and patient's perspectives.

The second part, 8.2, analyses the embedding of TUMT and PLFT into the four different hospital contexts, presented in the empirical Chapter 6 and focusses on specific level interactions, hence the analysis takes a starting point in a clinical level use of microwave technology in the four different hospital contexts. The most salient resource interfaces and identified drivers and hindrances will be discussed in both parts under the headings respectively of;

1) Science-based standardisation for embedding TUMT and PLFT in the Swedish public healthcare system (Section 8.1).
2) Multilevel complex adaptations for embedding TUMT and PLFT into medical practice (Section 8.2)

8.1 SCIENCE-BASED STANDARDISATION FOR EMBEDDING TUMT AND PLFT AT A SYSTEMIC LEVEL

In order to get a picture of what a new device actually has to relate to in terms of regulations when striving to become part of the Swedish public healthcare system, this section discusses aspects of embedding TUMT and PLFT at a systemic level by presenting some of the key interfaces identified from the case with following drivers and hindrances. The section starts with the most

salient control tools at a central level, in Section 8.1.1. Section 8.1.2 discusses the financial tools, which constitutes the direct interfaces at a specific level of use, yet influenced by systemic financial control tools and organisation. The section ends with a discussion regarding the interface between PLFT and the patient and physician respectively, in Section 8.1.3, for the purpose of presenting an alternative perspective on the value of microwave treatment from the individual user's perspective.

8.1.1 CENTRAL CONTROL TOOLS AND THEIR IMPACT ON THE USE OF TUMT AND PLFT

Since the first TUMT development in Sweden in the 1990s, the past two decades, starting around 2000, there has been an increased centralised control in public healthcare. At the same time as the public healthcare system is characterised by a high decentralisation, central regulations have increased. The increased central control implies that new devices, to an increasing extent, have to become approved at a systemic level in order to achieve widespread regular use within the whole national system. This section discusses the regulations in relation to TUMT and PLFT and therefore how the regulations were modelled from back in the mid-1990s up until about 2010.

- **Central assessments–TUMT** (OU–F):
  In the case of the TUMT device, central guidelines were not of great importance since there were less central regulations of healthcare in the early 1990s, especially for medical technologies. However, TUMT did not have any significant scientific documentation and the technology and its therapeutic method did not include any advanced methodology but was a simple low-effect treatment, a factor which added to the claimed 'easy-going' approach[55] towards the first generation of TUMT devices. All patients were treated using the same standardised therapeutic method and parameters, independent of the individual preconditions of the patient.

- **Central assessments–PLFT** (OU–F):
  PLFT entered the healthcare system in the early 2000s, a time when

[55] In the empirical chapters, it was mentioned that the first TUMT device was purchased by some hospitals despite the fact that it lacked documented scientific evidence, which was conduct that caused debate among Swedish urologists where, foremost, the university hospitals were critical towards this 'lax attitude'.

central regulations were increasing. In order for PLFT to become embedded at a systemic level and hence, enhance its chances of achieving widespread use, it needed to be assessed and approved by central agencies who normally base their evaluations on HTAs (Health Technology Assessments). Microwave technology as a treatment method was included in SBU's report on all available treatment methods of BPH in the Swedish system, which concluded that microwave treatment was the most common active BPH therapy next to surgery. However, the first time a central report mentioned microwave treatment for BPH problems was in 2011, 20 years after the first TUMT device was ready to be brought into use at the urology clinic in Örebro.

The basis for these central assessments is Evidence-Based Medicine. Therefore, it is of interest to analyse how the outcome of PLFT research relates to EBM practice.

- **EBM–PLFT** (OU–F):
  After 2010, there were a total of five independent dissertations that establish the usefulness of microwave-based methods in the treatment of BPH. All of these dissertations were defended at large university hospitals in Sweden, such as Lund University hospital, Uppsala Akademiska hospital and Sahlgrenska University Hospital in Gothenburg. Still, some urologists claimed PLFT was not an 'evidence-based' method. These urologists had read the results of clinical studies, but contended the results of the studies were not applicable to their own experience of using the device. These disputes show the difficulties accepting the 'static data', such as EBM, on a specific level. Despite the fact that many urologists had been involved in the development of both TUMT and PLFT, whether microwave technology was to be considered evidence-based or not was still subject to discussion. That treatment results vary between users is common practice since it is assumed to be context-dependent, as was argued earlier in the theoretical chapter. Likewise, the accuracy of academic results triggers discussion of facts and research findings among researchers, which certainly was the case with microwave technology. However, within EBM practice, facts are not questionable but regarded as static and objective, which creates questions regarding the accuracy and trustworthiness of data. We can contend that, in the case of TUMT and PLFT, there were diverge opinions.

- **Purchasing procedure – Urologists** (OU–OU):
  In a purchasing procedure, that normally takes place at a local level, the physicians are involved in the sense that they 'request' specific resources, devices, each year. A clinic that decides to request a purchase of a specific device has based that decision on available knowledge, scientific data and the current resource structure at their specific clinic. If the clinic is granted the purchase of a specific resource, they can partly participate in the construction of the product specification for the tendering procedure. Urologists have the capability, even if only a minor one, to influence the tendering contract utilised in the purchasing procedure.

- **Public purchasers – Microwave technology** (OU–F):
  However, the user interface soon changes in relation to the particular facility during a procurement procedure. The PLFT device is no longer evaluated by its direct users but by public purchasers. Further, the character of the interface is fundamentally altered. The interface during development had been between the direct users at the urology departments and ProstaLund. However, during a purchase procedure, the interface changes and involves only the public purchasers and the microwave device. It is a highly standardised and formalised interface where, first and foremost, technological and financial aspects of the device/technology are considered. For a provider of a medical device, it becomes a key issue to understand which features are important in the eyes of the purchasers (most commonly price) since technical features have to be generic in accordance with the competitive principle. Therefore, unique features, which previously were central to the direct users in the procurement process are no longer valuable. This public-private interface is highly formalised and totally different from the public-private interface identified during development, which was of an interactive character and based on a thick relationship. ProstaLund even changed their strategy towards healthcare because of the difficulties to embed their device since they were no longer focussed on achieving widespread use of their device among urologists, but focussed on healthcare managers and even politicians, in order to embed their device into use.

- **Education of urologists–PLFT** (OU–F):
  In the long term, embedding PLFT into public healthcare includes the

centralised issue of education and specialist training of urologists. The different procedures that physicians learn during their education are well established procedures that are regarded as the basic skills of the specialisation. Urology is a surgical subspecialisation and TURP surgery is 'the handicraft' of urologists and stated to be an important introduction to more advanced surgical procedures. Using more PLFT at the expense of TURP is at risk to create less opportunities for training urologists to practice their surgical skills and therefore affect other treatments negatively.

This section relates back to the empirical Chapter 5, discussing central regulations and how they affect the embedding of TUMT/PLFT into regular use in practice. It is possible to view regulations as a gatekeeper for new methods to enter the Swedish healthcare system on a larger scale, that is, widespread use. However, because of the decentralised organisation of the system, there is always the possibility that some counties purchase a new device despite its lack of central recommendations or guidelines. Table 8, here below presents the driver and hindrances over three pages.

REGULATORY DRIVERS AND HINDRANCES TO EMBED TUMT AND PLFT AT A SYSTEMIC LEVEL

DRIVER	HINDRANCES
Physicians' active participation in the purchasing procedure **–** The local purchasing procedures where physicians are active in choosing their methods is a driver to embed new methods into practice. As the physicians make assessments of the new methods in terms of financial, scientific and treatment efficiency, above which they also have exclusive knowledge about the resources in use at their clinics, which enables them to assess the actual contribution of the new device in practice.	***The difficulty to standardise the treatment procedure scientifically*** – In relation to EBM practice, it was difficult to standardise the treatment procedure – hence for all urologists to achieve about the same results when operating the PLFT device – which was a hindrance to embed PLFT at a systemic level. Despite several dissertations and long-term studies, there were urologists declaring PLFT not to be a well-established method, that it was not evidence based from their point of view. This illustrates the ambiguity in the tool EBM. The boundaries for what can be

	considered an EBM method are sometimes rather vague as are the assessment of the data, known as the 'grading system'. The fact that PLFT was a more complex treatment system than TUMT can potentially have added to the many diverging opinions of its usefulness in practice and affected the outcome of its scientific grading.
	Central assessments, like Health Technology Assessments (HTA) creates a 'catch 22'effect – A new method cannot be subject to an assessment unless it has been used over a longer period of time so as to provide enough data as a basis for the assessment. Likewise, new methods have difficulties to be embedded into regular use unless they have undergone a proper assessment by central authorities.
	Public procurement rules are a hindrance to public-private relationships – Relationships between users and producers are held to be crucial in order to achieve necessary adaptations when embedding new solutions into use. In the case of PLFT approaching regular use, the interface between PLFT and healthcare changes from being interactive in its character to highly formalised. The prior interactions that ProstaLund had with the clinics are not worth a penny in the procurement process. Open competition has a higher purpose than already established relationships and can easily override 10 years of joint development. In this case, procurement regulations did not affect the clinics in Kalmar and USÖ, which had developed their own devices and owned them; and in Lund and Uppsala the PLFT method was never fully embedded and

	therefore did not go through a procurement process. Yet, in 2010, procurement routines were described by ProstaLund as very problematic. ProstaLund tried to change focus, hence their interface, towards healthcare, from urologists to central purchasers, managers and politicians.
	Established treatment procedures in the education of urologists– At some point in time ProstaLund expressed that urologists seemed reluctant to use the PLFT device, independent of its treatment outcomes. It is possible to understand this 'reluctance' in relation to the stabilisation and standardisation of treatment procedures over time. This standardisation starts already in the education of urologists and is dominated by such surgical procedures as TURP. One may suggest that the training should be altered and focus more on educating physicians in new high–tech methods instead of clinging to old surgical procedures. However, the obstacle is that different treatment procedures are not easy to separate or exclude from a curriculum since they have overlapping functions. It explains why it is problematic to *replace* one method with a totally different one, despite the fact that they both treat the same disease. This conservatism underscores the strong path dependence for established treatment procedures. The interconnections between procedures and their functions in relation to each other are settled already in the specialist training of physicians. One central aspect from a urologist's point of view is how the PLFT device can create value in relation to other treatment procedures and fit into established structures.

Table 8. Regulatory Drivers and Hindrances to embed TUMT and PLFT at a systemic level

8.1.2 FINANCIAL TOOLS AND THEIR IMPACT ON THE USE OF TUMT AND PLFT

As for the financial aspects, a hospital department's activities are strictly regulated through financial monitoring tools such as budget and internal billing, which in turn are tools restraining a department's possibilities to introduce new methods into practice and undertake its activities. The regulations are found on many levels and can be described as both direct and indirect.

- **Department/Hospital Budget –PLFT** (OU–F):

Budget can be a strong monitoring tool which is illustrated well in the case of Lund's hospital where the budget was used to induce physicians to use microwave technology instead of surgery. With the intent of shortening the waiting time for BPH patients to receive treatment, politicians used the budget as a tool to steer the department's activities and influence which treatment should be the main procedure in the treatment of BPH. A very simplified financial logic triggered the temporary embedding of PLFT into use in Lund. The budget isolates cost items and if two methods, like TUMT and PLFT are compared out of context, it might be that PLFT generates lower costs. However, such evaluation does not take into account the costs of using PLFT in relation to already established treatment procedures.

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The financial tensions between microwave treatment and surgery can partly be understood through differences in their reimbursement. TURP is an inpatient surgical procedure and PLFT is an outpatient treatment striving to become established within the same system. It is not within the frames of this thesis to assess, which one of the reimbursement principles will generate higher or lower costs for the single department, the point here is simply to underline the two methods' different conditions in the reimbursement system and the consequences that it might cause for the embedding of PLFT into widespread use. Therefore, these two relevant interfaces can be identified:

- **TURP - inpatient treatment–Reimbursement DRG** (OU–OU):
  As an inpatient treatment, TURP is reimbursed through DRG, which means that this procedure also relies on a settled structure financially. A urology department thus has a clear picture of TURP's expenditures and incomes.

- **PLFT–DRG** (F–OU):
  Being that PLFT is accounted for outside the DRG system, by different logics, even if it treats the same disease, it becomes difficult for a given department/clinic to gain from using PLFT. Commonly, an investment in PLFT would generate financial benefits visible elsewhere at the hospital or in the system, such as lower costs in anaesthesia or at the central surgery department, but not in the urology department's budget. The single department rather stands alone with the costs of the investment and the related costs of adaptations. Other gains from a PLFT investment might also be found on a societal level, where patients can return to work faster thanks to a minimally invasive treatment and avoid longer periods of sick leave. However, these gains are not accounted for in the budgets of the departments which are expected to cover the investment.

  A recurrent theme in the empirical material was that the microwave treatment enhanced costs rather than reducing them at the level of the single department/clinic. The departments have often arranged their resources in accordance with the current logic of hospitals' provision of healthcare services, which is dominated by inpatient treatments. The outpatient reimbursement applied to PLFT procedures then breaches the current in-patient logic and it becomes difficult for smaller units to financially gain from utilising outpatient treatments due to current organisation of hospital activities and its reimbursement system.

This section provides only hindrances to embed PLFT into use. The organisation of accountability, budgeting and reimbursement altogether creates large hindrances to embed PLFT into use, the hindrances are presented in Table 9.

FINANCIAL HINDRANCES TO EMBED PLFT

HINDRANCES
The budget isolates cost items – The hospital budget isolates cost items and misses out on the interconnectedness of resources in use at the clinical level, within and between clinics. Without a proper understanding of the interconnectedness of current resource structures at a hospital level, for example the impact use of PLFT would have on the central surgery department, can have large consequences on the total output of healthcare at the single hospital. Isolation of cost items create considerable costs for the single unit, costs that in the end will reject change.

The contradiction between managerial and practice level decisions – The diverging logics behind decisions made in medical practice and managerial decisions, which commonly are based on purely financial fundaments, create clashes in the provision of healthcare services. Contradictory perspectives will be a hindrance to embed new solutions into use. The example of Lund clearly shows that what makes sense from a purely financial perspective – as for example to replace TURP with PLFT over night – does not necessarily make sense from the department's practice-based perspective. The 'financial perspective' isolates the disease, the treatment procedure and the cost of treatment from other established material and social resources and thus fails to capture the effect on related resources and the total cost of bringing the new solution into use.
Different reimbursement standards – An outpatient procedure, like PLFT, breaks with the current logic in the resource structure when it strives to replace an inpatient treatment like TURP. The fact that the two methods are accounted for by different standards further enhances the difficulties to embed new solutions like PLFT since their financial effects in the organisation are not comparable. Hence, even if less expensive per treated patient, the outpatient treatment, PLFT, brings less favourable reimbursement to the departments/clinics.

Table 9. Financial hindrances to embed PLFT into use

8.1.3 THE IMPACT OF SOCIAL FACTORS IN EMBEDDING PLFT AT A SPECIFIC LEVEL OF USE

The case has provided insights from physicians that have utilised the device and their opinions of its usefulness in relation to their everyday work at the clinic as well as to the needs among their BPH patients. These two interfaces are particularly salient at an individual use level:

- **PLFT– Patients unable to undergo surgery** (F–OU):
  From the perspective of patients unable to undergo surgery and in need of an 'active treatment', PLFT potentially is a treatment method of high value, since there is no other option available. This perspective could be contrasted to the 'financial view' of how to organise treatment methods. The financial perspective strives towards a logic of as few possible treatment procedures for each disease and can easily push out treatment methods favourable for a marginal group of patients.

- **Physicians' expertise–PLFT** (OU–F):
  Urology is a surgical subspecialty and surgery is what urologists preferably do. Therefore, TURP, the surgical standard procedure in the treatment of BPH, is considered to be "the handicraft" of urologists. Urologists continue to get comprehensive training in performing TURP and therefore i*nvest* in their surgical training. Within the professional field of urology surgical skills are well-embedded social resources with a strong path dependence, especially the TURP procedure, which stems from urologists' training. Since the outcome of treatment with medical technology devices is found to be contingent on the single physician's ability to operate the device, training is a central key to achieve embedding at a specific use level.

From the two interfaces presented above there are a number of hindrances identified, which is partly a consequence of the complexities of directly related resources' interconnectedness in practice. For example, the interface between physicians and PLFT contains many different layers that will affect PLFT's likelihood of becoming embedded into medical practice, therefore the same interface creates multiple hindrances.

HINDRANCES
Difficulties to replace established treatment procedures from a professional point of view – From a professional standpoint, the rationale is to continue to use the methods learnt during specialist training, other new methods can be added, but to replace established ones will meet a large resistance. Regardless, even if the urologist's professional standpoint of optimally treating *all* possible patients would induce the physician to keep several different treatment methods at hand, it would be practically difficult to do so. In the case of PLFT, this means that patients unable to undergo surgery could have a feasible treatment option, yet implying a marginal use. However, physicians have difficulties embracing new methods in the organisation since it sometimes means they have to abandon previously accumulated skills in other methods. Moreover, the organisation of public healthcare contributes to uphold established structures rather than opening them up for renewal, which leads us to the next hindrance:
Difficulties replacing established treatment procedures due to interrelated resources in practice – Physicians base their decisions to support the introduction of a new device into their clinic, on the knowledge of what basic procedures and devices are absolutely necessary to exercise their profession in relation to their patients. The healthcare system as a whole strives to have as few methods possible for each disease. New methods that interfere with, or try to partly or fully replace the established main procedures, will experience high resistance from the profession as well. This resistance was well illustrated in the case of Lund (which will be further analysed here below), where PLFT clashed with the whole established structure at the urology department. Physicians were acting 'rational' in refusing to adopt a new method that broke the established resource structures at the clinic: the high resistance was not due to individuals being overly conservative, rather their behaviour was reflecting the systemic endeavours of keeping available methods to a minimum.
Treatment outcome is correlated with extensive training – The outcome of treatment is contingent on physicians' ability to operate the device: limited training in operating the PLFT device minimises the chances for good treatment results and decreases the chances for PLFT to become embedded into use.
Economy as the norm for assessing efficiency – An isolated financial perspective dominating the decisions of which methods shall be brought into use hinders the embedding of TUMT/PLFT since such perspectives do not account for other important core values. The perspectives of physicians as professional caregivers and of patients as individuals with different needs can

potentially provide other answers to the efficiency of new methods, that can be equally financially relevant. It is in essence a question of how value is accounted for within the given frames of the organisation of public healthcare. The case of TUMT/PLFT makes it evident that it is neither the medical profession's perspective nor the patient perspective being the main determinants for how to account for efficiency and value in public healthcare. The fact that the financial perspective dominates the organisation of healthcare, makes the professional caregivers' and the patients' perspectives less significant: the system levels' very specific view of financial efficiency, hence stressing a logic for as few available methods as possible for each intervention, have become the norm for efficient organisation.

Table 10. Social hindrances to embed PLFT in medical practice

8.1.4 CONCLUDING COMMENTS ON THE SYSTEMIC LEVEL ASPECTS OF EMBEDDING TUMT AND PLFT INTO USE

The hindrances to embedding TUMT and PLFT into use are of *regulatory* and *social* character. Despite the different character of the hindrances, they are all consequences of the organisation of public healthcare on a systemic level. Thus far, it is possible to see the imprints of the regulation and control structures and how they affect even social resources at a specific level, via the linkages at the clinic where it creates hindrances to embed PLFT into continuous use.

From a medical profession perspective, it becomes evident that any new complex treatment method needs time to become embedded into the basic palette of skills that constitutes the fundament of a certain specialisation. The strong path dependence of treatment procedures has its origin in the medical profession and starts as early as the education of physicians. Yet, the current routines and regulations in public healthcare organisation stabilise established treatment procedures even further rather than promoting change. Since large-scale efficiency and accountability of smaller units are promoted within the NPM doctrine, any small change will take the proportions of a radical change and thus create large costs. Costs which are both indirect, in terms of adaptations of established social and material resources, and direct expenditures for investing in new technologies. Therefore, to create new processes in this kind of system demands large mobilisation of resources, leaving the single hospital organisation with small possibilities to introduce continuous changes.
Attributing financial responsibility over the resources in use at the clinic to

physicians (mainly heads of clinics/first line managers), alongside treatment/patient responsibilities, is another constraining issue. Hence, physicians' task is to provide the best possible care with given resources, implying they can choose which methods to use and how frequently to use them and how to combine the resources at hand in an optimal manner. However, at the same time, physicians only have a very formal control over the resources that are purchased for their clinic. The devices that physicians have requested might eventually be purchased, on the basis of generic and formalised product specifications, which gives no room for interaction with the providing company and thus very little room for either the clinic or the company to make necessary adaptations in the new device or established resources. This is a major paradox of the public healthcare system, where physicians have full financial responsibility over resources, but little control over the specific resources purchased for their departments. This is a consequence of the regulations and policies underlying homogeneity assumption, wherein the purchased devices will generate the same outcome anywhere in practice. The products and methods are assumed to have homogenous interfaces towards healthcare users. However, this is commonly not the case and the more complex and adaptable the interfaces that a treatment method has towards its users, the more probable a high variance in use. As is also visible in the refinement of TUMT into the more 'adaptable' PLFT.

The most evident paradox demonstrated by this case is that the very same budget responsibility that once triggered the chief urologist at USÖ to initiate development of a TUMT device then creates hindrances to embed the TUMT/PLFT device into continuous use in the other end of the innovation process. The decentralised financial responsibility holding each small unit financially accountable for finances can be a hindrance in that the single clinic does not have the financial muscles to alone make investments in a new technology. Additionally, the gains of the investment are often found somewhere else in the system. For example, the use of PLFT at a urology clinic would liberate time and capacity at the central surgery department at the same hospital but create an additional treatment procedure for the urology department and increase both its costs and workload.

8.2 COMPLEX MULTI–LEVEL ADAPTATIONS FOR EMBEDDING TUMT AND PLFT INTO MEDICAL PRACTICE

A pivotal point of departure in this specific innovation journey is that the TUMT-project aimed at *replacing* the existing standard treatment of BPH rather than to find 'yet another' treatment. The aim with the development was to create a more cost-efficient and patient-friendly BPH-treatment able to *replace* the traditional surgical procedure, TURP. However, the NPM steering reform does not only change the main reason to develop new methods, but also the prerequisites to bring new methods into use in medical practice. Large-scale procedures, internal billing, budget responsibility in each small unit, the rigidity of established treatment procedures, a narrow financial focus, increased central governance, to mention but a few, are aspects that affect the possibilities to embed the PLFT device into use. Some of these aspects were present before the introduction of the NPM doctrine and to embed something new into medical practice has never been a straightforward and easy task.

However, the NPM doctrine did not facilitate new methods being brought into continuous use. At the same time, NPM does not influence all specific using contexts of the level of their individual procedures equally; as we saw in the empirical chapters, the patterns of use of PLFT greatly varied. We shall now look closer at the four different hospital contexts to analyse what drove or hindered each context from bringing the PLFT method into continuous use.

8.2.1 UPPSALA AKADEMISKA: PLFT 'PARTIALLY EMBEDDED' INTO REGULAR USE AS A RESEARCH FACILITY

This department acquired a PLFT device for research purposes, but never brought the method into regular use, in the provision of healthcare services at the department.

- **PLFT–Urology department at Uppsala Akademiska Hospital** (academic setting) (F–OU):
  When the dissertation on the PLFT method had been defended, at Uppsala Akademiska Hospital (Uppsala A.H.), one could expect that the PLFT device would have been gradually embedded to finally become part of the regular provision of healthcare services, as a treatment facility. Such reasoning makes sense since it would imply a slow embedding of a new method into the provision of healthcare services

at the department, where knowledge and skills successively had become part of the whole department during clinical research. However, that was not the case; PLFT was never brought into regular use at this urology department.

- **PLFT–TURP competence independence** (F–OU):
  At Uppsala A.H., most BPH patients in need of active treatment receive TURP surgery, which is outsourced to a smaller, regional, hospital in Enköping. Consequently, the existing standard procedure is outsourced by Uppsala A.H. and PLFT becomes just an additional procedure, rather than a financially motivated replacement of a surgical procedure promoted by the urology department.

- **PLFT–Urology department at Uppsala Akademiska Hospital** (provision of healthcare services) (F–OU):
  In order to embed PLFT into practice, the department would have two options: either to let PLFT replace the surgical procedure of TURP, or divide the patients between the two methods. Treating patients with only PLFT could potentially be hazardous since there are patients that will be in need of surgical treatment. However, dividing patients between the two methods implies that PLFT would be used sporadically because the method is the most efficient only for a smaller group of patients, not large enough to sustain a standardised procedure. Also, to divide patients between the two methods would not generate large-scale effects to any of the two alternatives. Consequently, it was not financially motivated for this department to embed a second method like PLFT into continuous use.

At Uppsala A.H. PLFT was sporadically used, even though the device was never embedded into regular use in the everyday provision of healthcare services. At this department, the device was embedded into a research context as a *research facility*. Not having embedded PLFT into regular use in the provision of services system actually facilitates its infrequent use. As a research facility, PLFT is not encompassed by the extensive regulations, financial regulations (budget, internal billing, reimbursement, etc.) and organisational issues that are present at the 'service provision side' of the department. The use of PLFT is somewhere in between research and regular use, not all treatments performed falls within the frames of a PLFT-research project. Yet, the facility

as such is embedded in the research part of the department's organisation. Table 11, here below presents the hindrances identified, based on the interfaces above.

HINDRANCES TO EMBED PLFT INTO REGULAR USE AT UPPSALA AKADEMISKA HOSPITAL

HINDRANCES
'Hybrid use' in between research and provision of healthcare services – The fact that PLFT not fully could replace the standard surgical procedure, means that its function inexorably has to be as a *complementary procedure* to surgery. The effort towards large-scale procedures triggers this kind of 'hybrid use' and should be considered as an organisational key issue that hinders marginal treatment procedures to become fully embedded into the 'official' provision of healthcare services. To preserve PLFT as a research facility meant that this department could obtain marginal use of PLFT without disturbing the established large-scale procedures and was therefore, from the department's perspective, the most rational option. From an innovation process point of view, the 'hybrid use' will hinder the device to become embedded into regular use with the consequence that ProstaLund will have difficulties to get paid by this customer for actually using the device in 'the provision of healthcare services'. Therefore, persisting with 'hybrid use', in between medical practice and research, becomes a hindrance to the innovation process.
Large-scale procedures – Uppsala A.H. outsourced the TURP surgery to a smaller hospital in Enköping. To bring PLFT into regular use at the urology department would have brought the BPH procedure back to the hospital, causing additional costs in the treatment of BPH to the department. PLFT will experience difficulties breaking established large-scale procedures in an organisation like Uppsala A.H., since even an incremental change then takes the proportions of radical change. Thus, to embed PLFT into regular use at this department creates large costs that do not necessarily correspond to potential gains of the investment in a facility used on a 'marginal' group of patients. The necessary adaptations in order to embed PLFT as a fully complementary procedure to surgery would be too expensive and require exceedingly large efforts to make it worthwhile for the single department that alone would have to carry the costs for such adaptation.

Table 11. Hindrances to embed PLFT into regular use at Uppsala Akademiska hospital

8.2.2 LUND UNIVERSITY HOSPITAL: USE ENFORCED THROUGH A POLITICAL AGENDA WITH A STRONG FINANCIAL PERSPECTIVE

The fact that the PLFT method was challenging a well-established primary procedure is well illustrated in the case of Lund. When politicians decided to take actions to cut the long wait times to receive BPH treatment they, more or less, forced the clinic to treat the patients with PLFT.

- **Political decision to embed PLFT–The urology department's view on embedding PLFT** (OU-OU):
  The political decision to embed PLFT was based on a narrow financial assessment of its usefulness in the treatment of BPH and did not take any other aspects into consideration, for example such as already established treatment procedures. The political decision was executed based on budget restrictions, hence the department would have to cut down their budget unless willing to treat BPH patients with PLFT. From the departments perspective, using PLFT changed their activities from the ground, with consequences that reached far outside BPH treatment procedures.

- **PLFT–TURP procedures** (F–OU):
  The establishment of PLFT as a treatment device in regular use changed the organisation of activities at the department and therefore also the related activities, outside the department and the hospital of Lund. The previous main procedure in the treatment of BPH, TURP, had been outsourced to a smaller hospital within the county. Now that the BPH treatment procedure had been changed to PLFT, the BPH patients were instead treated at the urology department in Lund, which consequently got a new mass of patients and a new treatment procedure to handle over and above the established procedures.

- **PLFT–Established surgical procedures at the urology department** (F–OU):

  The PLFT treatment affected all activities at the department. More advanced surgical procedures, other than TURP, decreased in priority, which affected such issues as surgical training of specialists and other more advanced surgical procedures had to stand back in favour of

PLFT treatment. However, as soon as the waiting list to receive treatment for BPH was reduced, the department resumed the outsourced TURP treatment procedure and PLFT became a marginal procedure at the department. For example, urologists expressed that they missed out on important training when they were forced to use PLFT at their clinic. Since there had been no prior adaptations, PLFT pushed out other central treatment procedures. PLFT is a device which is not utilised in surgical premises but in open day care. Other treatments in open day care had to be reorganised as well, which took important time and efforts from the personnel to arrange, with the final effect that other important surgical methods had to be put aside in favour of using PLFT. In the end, the urology department in Lund provided less care on a total account when forced to use the PLFT method, since it was difficult to adapt related resources in provision of healthcare services.

The 'mini case' of Lund is interesting in that it was a political decision to embed PLFT into regular use and consequently PLFT was brought into use without having to pass through all the formalised regulations at a systemic and regional level, referring to such as purchasing procedures and centrally issued assessments. Despite the strong support of its use from a political/managerial level, PLFT did not succeed in becoming embedded into regular use at the department in Lund. The hindrances are presented in Table 12.

HINDRANCES TO EMBED PLFT INTO REGULAR USE AT LUND UNIVERSITY HOSPITAL

HINDRANCES
Narrow financial perspective on the value of new methods in use – The pattern of use in Lund clearly shows that the embedding of PLFT into regular use requires far more than one single perspective to assess the effects it will create in use. Otherwise, potential negative effects will emerge to hinder regular and permanent use of PLFT. Established social and material resources, including knowledge, learning, local practice and other competing procedures, will resist changes that are not fully prepared. To embed a device like PLFT permanently requests extensive adaptations within the existing organisation of healthcare practice. The fact that the use of the PLFT device did shorten the queues of patients waiting to receive treatment was not necessarily due to the higher efficiency of the device as such, but to a simple organisational decision to prioritise this method.
Financial perspectives dominate decision-making at a managerial level– The assessment of PLFT's efficiency on a political level, by the county directors, was based on financial estimates and the fact that PLFT was a seemingly 'faster' and less expensive alternative than the surgical procedure of TURP. Regardless, the overall consequences, on related procedures and the costs brought by such reorganisation was not part of the policy initiative and in the end, hindered PLFT from becoming fully embedded, as a permanent facility in continuous use at the clinic.
Established procedures have an overlapping function – It was not possible to fully replace the method TURP because it was embedded into a larger web of several procedures with overlapping functions. TURP had important interfaces towards other surgical resources, which PLFT could not replace despite its clear short-term efficiency in cutting patient queues.

Table 12. Hindrances to embed PLFT into regular use at Lund University hospital

8.2.3 ÖREBRO UNIVERSITY HOSPITAL (USÖ): AN ALTERNATIVE USE IN A NEW TREATMENT AREA

It was this department that initially triggered the development of TUMT. The following interfaces are particularly salient in framing use in the context of USÖ:

- **TUMT–Urology department at Örebro University Hospital** (USÖ) (F–OU):
  When it was clear that TUMT would never become a standard procedure able to fully replace TURP surgery, the department found another way to profit from their investment. As the TUMT device already was a facility owned by the department and embedded into their 'provision of healthcare services' it could be used in another treatment area without any larger efforts (prostatitis). The device was owned and controlled by the department that freely could choose how to economise upon this specific resource.

- **TUMT–Prostatitis treatment procedures** (F–OU):
  The first generation TUMT was a low effect device: its effect on the prostate was minimal and therefore better suited for the treatment of prostatitis (a less serious form of irritation in the prostate gland). To change the area of use was therefore perfectly logic from this single department's perspective. They had invested substantial amounts of resources into the development of a device that was customised for their organisation. The department had related investments in place already at a development stage and had to economise upon their investment. TUMT became accordingly embedded as a device in the treatment of prostatitis. Making this embedding possible, a pivotal factor was that prostatitis did not have an established treatment procedure of its own: therefore, there was nothing to replace and hence no conflict over standard procedures in this category of patients. Also, TUMT had already been given a place in the regular 'service provision structure' at the USÖ Urology department and was not a new device: it was an embedded production facility at the department.

- **TUMT–Established surgical procedures (F–OU):**
  The urology department in Örebro is also somewhat special in the sense that it has its own surgical premises and surgery was never a

bottleneck in this organisation. TUMT or PLFT were never widely used at this department for BPH, but organisationally it would not have had any larger impact on other surgical procedures.

In regard to BPH treatment, this department did not succeed to fully embed neither TUMT nor PLFT. However interesting is that this clinic found a new treatment area for their device, which was a way for this specific department to economise upon earlier investments and therefore considered as drivers to the innovation process. They are presented in Table 13.

DRIVERS TO EMBED THE TUMT DEVICE INTO REGULAR USE AT USÖ

DRIVERS
Ability to control resources at the department – The driver to embed TUMT was that the department had invested its own resources in developing the device and wanted return on their investment. The fact that the department directly owned the facility made it easier to modify its area of use and decide how their specific organisation could best economise upon the investment.
Ability to economise resources by different means – The specific level use at USÖ shows how this organisational unit found a new, unexpected way to economise upon a resource over which *they had direct control*. Normally departments acquire resources with a preconditioned use and they are not authorised to freely choose or manage the resources in use at the departments. However, since Örebro had constructed this resource themselves, they had full control over how to utilise and economise upon the specific resource, TUMT.

Table 13. Drivers to embed the TUMT device into regular use at USÖ

8.2.4 KALMAR REGIONAL HOSPITAL: PLFT IN REGULAR USE IN HEALTHCARE PRACTICE

Just as the department in Örebro, this clinic was involved in an intense technological development of the PLFT device, which is reflected in the high degree of regular use. The following resource interfaces were relevant for this outcome:

- **PLFT(F)/ Urology clinic at Kalmar Regional Hospital** (F–OU):
  The PLFT device is embedded into this clinic's activities in a very well-defined way: Both with regard to schedules as diagnosis as well as in relation to other treatment procedures. It did take almost 10 years, even for this small clinic with extensive knowledge, to establish a routinised treatment procedure around this 'new' solution.
- **PLFT–TURP procedure** (F–OU):
  Despite the small size of this hospital, surgery is a bottleneck in this organisation (differently than USÖ). As a consequence, TURP surgery is outsourced to an even smaller hospital. But the Kalmar clinic does not send all 'operable' patients to surgery, instead this clinic has created an alternative way to make use of their prior investments in the development of the PLFT device. They have created a more refined diagnostic procedure adjusted to assess and decide, with great precision, the use of two main procedures, PLFT and TURP, which resulted in more patients receiving PLFT treatment.
- **PLFT–Diagnosis routines and knowledge** (F–OU):
  The diagnostic classification is not based on the use of surgery. Kalmar urologist's starting point was rather in the actual prostate troubles. An evaluation of size and type of troubles and the 'character of the prostate gland', allowed Kalmar's physicians to see that some prostates are better suited to surgical treatment and others for PLFT treatment. Even if other departments utilise the same kind of diagnosis criteria, a larger number of patients received traditional surgery at the other clinics. Microwave treatment was reserved for marginal use in most other departments and only for patients who, under no circumstances, could undergo surgery. Consequently, patients that would have been classified as "operable" at some of the large hospitals would in all probability instead have received PLFT treatment if treated in Kalmar where the division between the two methods at the time for this study was 65% TURP and 35% PLFT.

DRIVERS TO EMBED PLFT AT THE KALMAR UROLOGY CLINIC

DRIVERS
Time to adapt established resource interfaces to the new – The urology clinic in Kalmar made initial investments in the development of PLFT that, over time, made the PLFT device deeply embedded into that specific department's resource structure. The development of PLFT was time consuming, but gave the already established resources time to successively adapt to the new social and material resources, created in the development of PLFT. There was thus an ongoing mutual adaptation taking place, between the new, PLFT and already established resources. The new resources, complementing PLFT, are specifically salient in the treatment and diagnostic knowledge among the personnel of the Kalmar clinic. This extensive and deeply embedded knowledge was decisive for a successful embedding of PLFT.
Easier to achieve change in smaller healthcare organisations–The fact that Kalmar is a small hospital gave this organisation greater capability to alter existing procedures and create organisational space for a new facility like the PLFT. Flexibility is correlated with the size of the hospital and was a pivotal precondition to embed PLFT into regular use.

Table 14. Drivers to embed PLFT at the Kalmar Urology clinic

Kalmar is the only clinic where PLFT was fully embedded into continuous use, which makes it particularly important to consider the main drivers to embed PLFT in this use context. The fact that Kalmar succeeded to embed PLFT into regular use can be explained by the fact that PLFT was technically developed and constructed at this clinic. The device had time to develop interfaces towards the established resources, social as well as material. As for example, new knowledge had the capability of evolving over time and the healthcare personnel could build a profound understanding of the effects of the PLFT treatment. Likewise, organisational procedures had time to adapt to a more encompassing and continuous use of the PLFT treatment. However, the fact that it took almost 10 years, from initiating the project to achieving a fully embedded and regular PLFT-based treatment procedure, point to the organisational complexity of embedding a second treatment procedure for active BHP treatment. This local use context underlines the importance of time and adaptation. The knowledge of microwave treatment which is embedded into this clinic is a consequence of *technological development, mobilisation of substantial resources* and *close interaction* with the company ProstaLund, over *time*.

8.2.5 CONCLUDING COMMENTS ON THE SPECIFIC LEVEL USE OF TUMT/PLFT

The case and especially the four embedded user cases underlines that the specific level of use is heterogeneous: the four contexts provide various use and various possibilities to create value out of the TUMT/PLFT device. The drivers and hindrances deriving from the interfaces in each of the cases are overlapping, or even the same kinds of hindrances and drivers found in the interfaces at a systemic level. It leads to the conclusion that the systemic level make visible imprints in the interfaces in the specific level.

A general and not very surprising conclusion based on all four user settings is that embedding TUMT/PLFT into use took place where the device could follow investments in place and where there had been a deep involvement in its development, especially the technical one, rather than the scientific one. The fact that PLFT never became embedded into the Örebro department is not surprising since PLFT was a new device for this clinic, far more technically advanced than ‘their own’ TUMT device, and consequently did not follow investments in place. What the case underlines is that despite the users’ struggle to find a more efficient treatment method for BPH treatment and their

own outspoken need in clinical practice, it was still very challenging to create value from the device in practice.

The case of Lund provides an interesting framing in that the use of PLFT was induced as a policy top-down initiative. Therefore, the PLFT device was pushed through the system defying all of the normal regulatory hindrances of tendering and procurement procedures. Moreover, in the end, the social hindrances in practice and the very strong path dependence of established procedures, stemming from a medical logic, overruled the policy decision and clearly opposed the permanent and continuous embedding of PLFT in Lund.

9. DISCUSSION OF RESULTS

This chapter addresses the research questions of the thesis by summarising and discussing the results of the analysis from the previous chapters. The first research question was posed as follows:

Which are the main drivers and hindrances to embedding the microwave device into a) developing b) producing and c) using settings that emerge from private-public interactions?

Table 15, systematises and summarises the drivers and hindrances– over the three settings of, developing, producing and using– as presented in the analysis above. The table shows that the innovation process as a whole appears imbalanced, as does the distribution of drivers and hindrances in the three settings. The drivers are dominating in the developing setting, whereas the distribution of hindrances and drivers in the producing setting are rather even. The major part of hindrances appears instead in the using setting.

To answer the first research question, the key drivers and hindrances of each setting will first be discussed separately. However, the using setting discusses specific and systemic level drivers and hindrances separately and ends with an extended discussion on the interrelation between systemic level and specific level drivers and hindrances.

DRIVERS	HINDRANCES
Developing	
-Regulatory o *Regulatory changes create financial incentives and triggers the development of TUMT* o *NPM create imprints and stimulates the development of TUMT and PLFT* o *Financial incentives in the technological dev.* -Multiple sources of resources o *Broad international context* o *Indirect interfaces* -Organisational interaction o *Relationships and open interaction* o *Public-private interaction enables the development of TUMT* -Scientific o *PLFT gains scientific relevance when embedded into an academic setting* o *Scientific evaluation enhances the chances for PLFT to become embedded at a systemic level* -Financial o *Public financial support from procurement* o *Public financial support from the County of Kalmar* o *Public financial support from NUTEK*	o *The TUMT technology is insufficient in the treatment of BPH (This hindrance would later appear as a trigger to the further development of TUMT into PLFT)*
Producing	
o *New business relationships* o *Growth of ProstaLund's internal organisation* o *Public and Private funding*	o *Increased technological complexity* o *Increased costs to embed PLFT into production*
Using	
o *Physicians' active participation in the purchasing procedure (local use)* -Context-specific level – the 4 mini cases o *Capability to control resources at the department* o *Opportunity to economise upon resources in different ways* o *Time to adapt established resource interfaces to the new ones* o *Easier to achieve change in smaller healthcare organisations due to higher flexibility*	-Regulatory o *The difficulty to standardise the treatment procedure scientifically* o *Central assessments, like Health Technology Assessments (HTA) creates a 'catch 22'effect* o *Public procurement rules are a hindrance to public-private relationships* o *Established treatment procedures in the education of urologists* -Financial o *The budget isolates cost items* o *The contradiction between managerial and practice-level decisions* o *Different reimbursement standards* -Social o *Difficulties replacing established treatment procedures from a professional point of view* o *Difficulties replacing established treatment procedures due to interrelated resources in practice* o *Treatment outcome is correlated with extensive training* o *Finance as the norm for assessing efficiency* -Context specific level - the 4 mini cases o *'Hybrid use' in between research and provision of healthcare services* o *Large-scale procedures* o *Narrow financial perspective on the value of new methods in use* o *Financial perspectives dominate decision-making at a managerial level* o *Established procedures have an overlapping function*

Table 15. The drivers and hindrances in the innovation process of TUMT/PLFT

THE KEY DRIVERS AND KEY HINDRANCE IN THE DEVELOPING SETTING:

The developing setting mainly provides drivers to the innovation process of TUMT/PLFT (Table 15). The drivers are divided into five main categories; *Regulatory, inter-organisational interaction, multiple sources, financial, and scientific.*

The *regulatory* changes in public healthcare, brought forward through the NPM doctrine, created financial accountability of smaller units, which in turn triggered the first development of TUMT. The department searched for new methods capable of reducing the costs of BPH treatment. The regulatory changes created a *financially driven* incentive to develop TUMT and to enhance the efficiency of the provision of healthcare service. The regulatory changes driven by the NPM doctrine also created imprints in the further development of TUMT into PLFT in that it settled the conditions for future use. Hence, TUMT had to *replace* the standard procedure TURP, a condition that pushed the device's technological development even further in order for it to achieve individualised results compatible with the surgical treatment TURP. Therefore, the financial perspective, born out of regulatory changes, was a key driver throughout the technological development of TUMT and PLFT.

Another key driver was the *multiple sourcing* of this innovation. The larger 'historical perspective' featured the device's development in an international context, where it travelled between scientific arenas and business contexts that further developed and tested the device. Along these lines, the TUMT and PLFT development could benefit from ProstaLund's international network and TUMT's previous development, which contributed with solutions to technical problems arising along the way. The multiple sourcing further underlines the non-linear nature of innovation processes and the fact that they seldom are born within closed innovation systems.

Organisational interaction was a key driver in technological development. The ability to create close interactions in the public-private interface, hence inter-organisational relationships, was a pivotal resource to achieve development. The relationships should be regarded as a resource per se, carrying both direct and indirect social and material resource interactions. The interaction patterns underlying the development taking place between ProstaLund and USÖ and later ProstaLund and Kalmar, were thick relationships involving interaction of material and social resources.

The *scientific development* of PLFT was a key driver to embed PLFT into an academic setting and facilitate future possibilities to widespread use. The systemic assessments of new methods rely on scientific data, thus requiring that new solutions have scientific anchoring.

The scientific development differed from the technological development in that it was characterised by weaker public–private interactions and did not have an explicit financial motivation. Instead, the interfaces underlying the interaction between Uppsala Akademiska Hospital and ProstaLund were less profound and did not primarily revolve around technological development. The urology department at Akademiska did not have any outspoken incentives to embed the PLFT device into regular use, instead it was embedded as a scientific research tool.

A fifth key driver was the *financial support*, in terms of public funding from both healthcare and innovation support agencies. The parties involved in the technological development were small organisational units: initially a single person consultancy firm and a small urology department at hospital that at the time lacked central funding for engaging in research and development projects. In a case like this, public funding is crucial, not only initially, but also during the further development from TUMT to PLFT. Furthermore, the public support from NUTEK in the development of PLFT was necessary to overcome the single key hindrance in the developing setting:

The *highly-standardised treatment* provided by the first TUMT device was a hindrance to the innovation process. The lack of an individually adjustable treatment procedure hampered the further proliferation of the first TUMT device. TUMT could not achieve results compatible with those of surgery[56], which almost made ProstaLund go out of business and microwave technology disappear as treatment in Sweden. However, the standardised treatment procedure, identified as the cause reducing the performance of the device, later

[56] In relation to technological development there were many minor technical issues to overcome during the development of TUMT and PLFT, which is a common trait in technological development. However, in terms of hindrances and drivers in the innovation process, these *minor* technical hindrances or problems are not of focal interest to understand the overarching problems in the innovation process. Therefore, I have paid attention only to the larger technical changes as key drivers or hindrances. The 'minor' technical interfaces serve as a way to understand the character of the interaction between organisational units (see the method in Chapter 3 for further discussion). The fact that the first TUMT-technology was too standardised was thus such major technical deficiency that almost made the company ProstaLund go out of business.

turned out to be a trigger for its further development. An individualised treatment procedure could potentially realise the initially anticipated value of the device as cost efficient and patient-friendly treatment procedure. Aided by *Public innovation support*, the company could continue to develop the technology further together with Kalmar hospital.

THE KEY DRIVERS AND HINDRANCES IN THE PRODUCING SETTING:
The key hindrances and drivers influencing the innovation process in this setting are related to enabling large scale production of the more technologically advanced device PLFT, (see Table 15). The fact that ProstaLund succeeded to become embedded into a partly new production network is pivotal to the innovation process. Embedding their production activities in a larger production network enabled ProstaLund to create large-scale production processes of their device at a feasible cost, despite its technical complexity. Not only the development of the PLFT device required financial support, the establishment of new production processes demanded new investments and external capital. What this setting shows is that production is an equally resource-intensive and complex process that requires investments in production networks. A new device does not automatically move into production. The first TUMT device to a large extent had been produced 'in-house', but PLFT was more technically advanced and ProstaLund could not handle large-scale production in-house at a feasible cost.

However, the decisions made in this setting by venture capitalist and public fundraisers to invest in ProstaLund and scale up the business was based on the fact that the device already was partially embedded in different healthcare contexts, both technologically and scientifically. There were potential customers willing to pay for the new solution. However, the producer's knowledge about their customers was based on the needs among the directs users, in clinical practice, not the requirements at a systemic level.

THE KEY DRIVERS AND HINDRANCES IN THE USING SETTING:
In the using setting, the hindrances heavily outweigh the drivers (see Table 15). The key *hindrances* in the using setting derives both from systemic and specific level aspects of use; the systemic level provide hindrances that are *regulatory, financial and social*, whereas the context-specific hindrances are identified from the specific level in the four mini cases. The *key drivers* in the using setting are found only in the specific level of use.

Systemic level drivers and hindrances

The *regulatory* hindrances include the difficulties to standardise PLFT scientifically through central assessments by the standards of knowledge management tools, such as EBM or centrally established guidelines in the training of urologists. The regulatory hindrances also concern procurement regulations, which hinders all possibilities to public-private interaction in the using setting. ProstaLund specifically underlined that they, in 2009, strived to build new relationships with hospital managers and influence at a political level in order to embed their device in the Swedish public healthcare system. As compared with their previous well-established relationships to their direct users in medical practice. The interface between ProstaLund and their users is essentially altered in comparison to the developing setting. The private–public interface is, in the using setting, highly formalised with no opportunities for interaction.

The *financial* hindrances revolve around responsibility structures built into the organisation of public healthcare. Specifically, this case points to such issues as silo budgeting, isolation of cost items and diverse reimbursement standards, creating rigid financial evaluations of new methods.

The large paradox appears as the internal billing system, holding smaller units financially accountable for their operations, simultaneously prohibits the units from having any influence over the resources purchased for their units. Purchases are handled through the purchasing function. Physicians can, to some degree, decide upon which kinds of resources they would like to use at their departments, however without any closer specificity to the actual material or social properties of the resources purchased. This is a consequence of the procurement regulations and policies underlying homogeneity assumption: the purchased devices are assumed to be generic and to generate the same outcome anywhere in practice, independent of context.

A central issue to the progress of the innovation process is the dominating position of the financial perspective. In the case of PLFT, there are potentially multiple other arguments for using the device, which could be just as valuable, such as the professional caregivers' or patients' perspectives, that plausibly would generate a different composition of treatment options available. For example, to have many parallel treatment options for the same disease and even procedures that cover a marginal group of patients. The current perspective represents an economically rational view of efficiency, favouring the purely financial aspects of use and which clearly delimits the variety of treatment options available. Pursuing large-scale procedures with narrow financial

perspectives is a hindrance for new methods and does not allow for, at the very least, marginal methods to be embedded into use.

The *social hindrances* are correlated to a centrally established path dependence which creates hindrances to make adaptations at a specific level. Established treatment procedures also make it difficult to replace old procedures from a professional point of view. For example, urologists have already invested time in developing their surgical skills, which in turn are interrelated to a number of different surgical procedures, procedures that are overlapping. The dexterity developed in performing TURP surgery is a necessary platform in the professional development towards more complicated surgical interventions. Furthermore, the social resources and how they are interconnected at the single clinic or department is difficult to map or detect from a financial or systemic perspective. Social resources are deeply embedded into the practice of healthcare personnel through education and training, but also in relation to the specific resource structure at each clinic. The case of PLFT/TUMT indicates that social resources at large play a crucial role in the successful embedding of new methods into regular use.

Another aspect is related to the current 'production-focussed' organisation of public healthcare: there is little organisational space to provide training in new methods that lies outside the regular specialist training programme. To embed a new device requires 'organisational space' at many different levels, not only in terms of physical structures, but on a social resource level as well. In order to create regular use of a new device, it is not enough that one single physician can operate it. Establishing *regular use* is a question of achieving continuity for PLFT as a 'production facility'. The major part of the personnel has to be able to operate the device properly and in order to achieve good results in treatment they need to get proper training and education. It is not possible to create continuity in usage being reliant on a single operator.

Specific level drivers and hindrances

A pivotal lesson from the mini cases is that regular use of TUMT/PLFT is strongly *context-dependent in the specific level of use,* i.e., within the single clinic. All of the four hospital contexts handled the embedding of the TUMT/PLFT device in different ways and also, to some degree, had diverging incentives to embed the device.

- At Uppsala A.H., the PLFT device was embedded as a *research facility*. The incentive to take this device into use at the urology department was research driven. Using PLFT as a research facility, the device did not interfere with existing large-scale procedures and did not generate any 'production costs' to the department. It could still be utilised in the marginal group of patients that cannot undergo surgery without being part of the healthcare provision system, thus creating a 'hybrid use', in between provision of healthcare services and research.
- Lund, utilised the PLFT device as a '*production facility'* in the provision of healthcare services, but only over a restricted time period in order to cut the waiting time to receive BPH treatment. TURP remained their main procedure in the treatment of BPH when the waiting time to receive treatment had been reduced. The case of Lund underlines the deep embedding of social resources in the professional training of health personnel and how such logic counteracts the 'financial logic' maintained by management and policy.
- USÖ used the TUMT device as a '*production facility'* and even found a new treatment area in prostatitis when it turned out to be less efficient in BPH treatment. The change of treatment area was a way to economise upon made investments in the technological development of the first TUMT machine. USÖ had the freedom to change treatment areas; since they had full control over this device, they had developed it themselves and thus customised it to their specific needs. They had extensive knowledge of its technical and social properties and therefore also the knowledge to change its area of use so as to suit the established treatment structure.
- Kalmar is the only hospital that have succeeded in embedding PLFT as a *regular treatment procedure* in the provision of healthcare services. Yet, it took the hospital almost 10 years to establish a fully integrated PLFT treatment procedure. One key factor is that the whole personnel has extensive knowledge in PLFT treatment and its related processes: how to use the device and create organisational space. This

clinic not only has adapted diagnostics and has a full working force able to operate the device, they also have a more-or-less fixed number of patients being treated with PLFT each year. An organised continuity in treatment which is not sporadic or random. The time factor is also pivotal. Kalmar was involved in the *technological development* of the device, thus following its pitfalls and advantages as the device developed technologically, but they have also integrated new scientific data and knowledge into their treatment procedure over time. Taken all together, this clinic *mobilised substantial resources* to embed the device into regular use. The *close interaction* with the company ProstaLund is also a driving factor in the clinic's ability to embed the device successfully in that the company could provide valuable support to the clinic.

We can conclude that each hospital economised upon the TUMT/PLFT facility in different ways, despite the fact that they treat the same disease, the fact that physicians supposedly have the same education and the fact that treatment is undertaken at hospitals within the same public healthcare system.

How Systemic and Specific level drivers and hindrances are interrelated in the using setting

Scrutinising the hindrances in the systemic and specific levels of use more closely it becomes evident that they are concurrent. For example, "*Narrow financial perspective on the value of new methods in use"* and "*Finance as the norm for assessing efficiency"* (see Table 15) emanates from the very same problem[57], however *derived from different interfaces*. Alternatively, "*Established treatment procedures in the education of urologists*" and "*Established procedures have an overlapping function*". The systemic regulations, including such as organisation of the system, knowledge management tools and economic organisation, trickles down to the specific level of use where it creates similar obstructing effects on the innovation process. Leading to the conclusion that hindrances at the specific level of use are closely interrelated to the hindrances at a systemic level (see Figure 7). While related, they are underpinned by different resource interfaces and therefore represent different kinds of hindrances to the innovation process. Moreover, the systemic level hin-

[57] That instruments utilised to evaluate new methods mainly focus on isolated economic features, hence out of context evaluations.

drances cannot be directly translated so as to create explicitly defined hindrances at a specific level in general. However, it is possible to see how they create boundaries to resources in practice. The kinds of hindrances coming out of such boundaries depend on the underlying resource interfaces in each unique case. Nevertheless, in this specific case, the hospital organisations explicitly push a large-scale rationale, a dominating financial perspective and follow the norms given prominence at a systemic level.

If the hindrances showed a clear interconnection between the systemic and specific levels, the drivers identified at the specific level are instead distinctively disconnected from the systemic level. Scrutinising the *drivers* more closely, we see that the systemic level lacks drivers to the PLFT/TUMT innovation process. *All of the drivers* derives from the *specific level* resource interactions and almost all of the *drivers*[58] in the using setting are found in the context specific mini cases that represents aspects of use where systemic norms and values have been disregarded and replaced with context specific values and assessments.

[58] The driver '*physicians' active participation in the purchasing procedure*" is potentially important to the establishment of new methods in the public healthcare system. This is a *local* level driver, e.g. county/hospital. Furthermore, physicians are not obliged to 'request' new devices, but are given the opportunity to do so through the yearly 'request list'. But these are locally governed procedures that vary between counties.

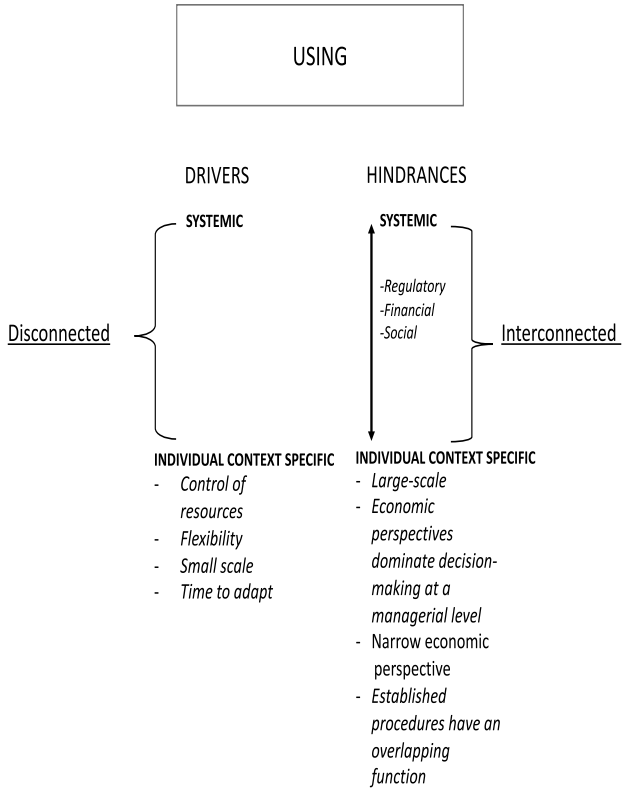

Figure 7. The interconnection-respective disconnection between systemic and specific level drivers and hindrances to use TUMT/PLFT.

One driver relates to the specific level in a general sense, which is the physicians' ability to participate in the *local* purchasing procedures. Physicians at a specific clinic have the best knowledge about the established material and social resources in use at their clinic and can thus contribute with valuable information in the purchasing procedure and presumably enhance the probability of creating a product specification that best corresponds to the specific clinic's needs. As such, to have a physician participating in the purchasing procedure increases the plausibility for a successful embedding of a specific device into regular use.

From this overarching picture and this specific case, med-tech innovation does not encounter its major problems in the developing or producing settings but in the using setting. To develop and produce a new medical technology certainly demands large efforts and a massive mobilisation of resources, which

was present in both the development and producing setting of TUMT/PLFT. However, in the using setting, only the smaller departments/clinics that had been involved in the long and exacting *technological* development succeeded in embedding the TUMT/PLFT device into regular use. However, also requiring organisational efforts from these small clinics, above the efforts of developing a new device.

The next research question concerned the interrelation between the drivers and hindrances in the different settings and was posed as follows:

ii) How are the key drivers and hindrances in the developing, producing and using settings interconnected?

First it has to be properly underlined that each of the three settings, developing, producing and using, follows their own logic and they do not have to be interconnected in order for innovation take place. Nevertheless, a new technology has to be embedded into each of these settings in order for innovation to be achieved. Without interconnecting the settings per se or interfering with their intrinsic logic, it is still of interest to understand the ways in which the key drivers and hindrances in the TUMT/PLFT innovation journey, are related in the med-tech innovation process at large.

The discussion will be based on two starting points. The first provides a comparison between a few of the key drivers/hindrances amongst the different settings. The second discusses how the key drivers and hindrances in the developing, producing and using settings are related.

COMPARISON OF THE KEY DRIVERS IN THE DIFFERENT SETTINGS OF THE TUMT/PLFT INNOVATION PROCESS

The key drivers are foremost present in the developing and producing settings and absent in the using setting. Even so, what initially functioned as a key driver, the financial organisation of public healthcare triggered by the NPM doctrine in the early 1990s, becomes a hindrance in the using setting (see Table 16 for a schematic overview).

	Developing	Producing	Using
a	NPM doctrine– financial accountability of smaller units (clinics) create incentives to initiate development of TUMT	-	NPM doctrine– financial accountability of smaller units and financial organisation of public healthcare hinders use
b	Financial support	Financial support	No financial support
c	Close interaction	Close interaction	No capability to direct user–producer interaction
d	Flexibility - good capability of making adaptations in indirect interfaces in the public-private interface	Flexibility - good possibilities to make adaptations in indirect interfaces in the production network	Stability- difficult to make adaptations in indirect interfaces in the healthcare organisation

Table 16. The uneven distribution/effect of key drivers in the different settings of the innovation process.

a) *The innovation process is simultaneously triggered and hampered by the new financial accountability, spurred by the NPM doctrine*. The system-wide NPM doctrine brought new financial measures in the early 1990s and was one of the main triggers behind the development of TUMT. However, in the using setting, the very same principles instead constitute financial and regulatory hindrances to the innovation process, at both a systemic and specific level of use (See Table 16 above).

b) *The financial support from public and private funding, varies over the three settings*. PLFT did not have any financial support in the using setting, however garnered crucial support in both the developing and producing settings, from public healthcare, innovation support agencies and private capital.

c) *The possibility to interact and freely choose partners– inter-organisational interaction patterns vary over the three settings*. The public–private interface changes over the settings, from being interactive in the developing and producing settings to become formalised and separated from the direct users in the using setting. Both the developing and producing setting had vast support in terms of how the 'scene was staged': a possibility for public and private organisations to interact openly. However, in the using setting, open interaction is prohibited and replaced with highly formalised contracts. Hence, the producer's interface towards their customer has changed, from being interactive in nature and involving the direct users to highly formalised relationships with public purchasers.

d) *Organisational flexibility and possibilities to make adaptations in direct and indirect resource interfaces varies over the three settings*. Another similar contradiction is visible if comparing the driver category '*multiple sources*' in the developing setting to the *'social hindrances'* category in the using setting (see Table 15). Both categories are based on PLFT's/TUMT's *indirect interfaces*. In the developing setting, the innovation process was characterised by high flexibility and even the *indirectly* related resources were a valuable and necessary source in the progress of the development. Yet, in the using setting, the systemic level consider indirectly interfaces as irrelevant to the assessment of new solutions' value in regular use. At the specific level, the established resources are deeply embedded[59] in the healthcare organisation, making it difficult to create changes in directly and indirectly related interfaces. The stable structures in the hospital organisations will resist rather than encourage change. The opportunities for PLFT to become embedded into regular use depends on the ability to make adaptations in both directly and indirectly related interfaces, hence organisational flexibility.

The comparison shows that the very same resources can create opposing effects in the different settings. Two settings, development and use, are to a large

[59] The deep embedding is a consequence of large-scale structures and of the many levels of interconnection in each interface. For instance, the interface between the surgical procedure TURP–Physician is embedded through urologists' specialist training at a central level, but also in terms of a professional investment for the single physician and last in relation to other, more advanced, surgical procedures that the physician has to master.

extent based on the empirical conditions of technological and business development whereas the using setting foremost is based on ideas of a market model ideal. A comparison of the settings then explicates the conflicting effect that they exert on the innovation process. For instance, applying the systemic perspective of the using setting on the developing and producing setting, many of the identified key drivers in this study transform into direct hindrances, because they counteract market model core values. The systemic organisation of public healthcare actively strives to *prohibit* functions that have been identified as key drivers in this study such as *interaction*, *contextualised use* and *flexibility* in the hospital organisations, since they cancel out the systemic organisation's core values; competition, standardisation and large-scale procedures.

CONNECTING KEY DRIVERS AND HINDRANCES IN THE INNOVATION PROCESS

The key drivers and hindrances identified in the settings are indeed interrelated and impinge on each other in different ways. This section will discuss what patterns can be discerned from this study. To simplify the discussion somewhat, only the drivers are represented in the developing and producing settings, whereas both drivers and hindrances are discussed in the using setting since they are equally significant to understand the main features of the interconnections in the innovation process as a whole. It is schematically described in Figure 8.

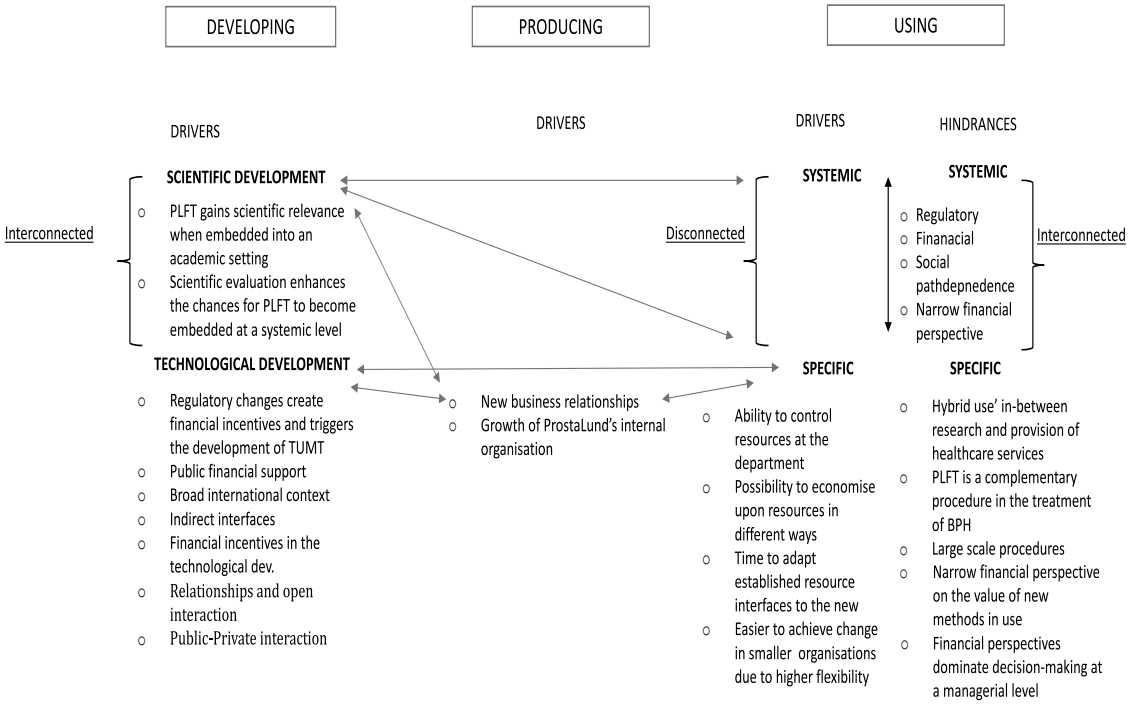

Figure 8. The interconnections between key drivers and hindrances in the developing, producing and using settings.

HOW SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT RELATES TO SYSTEMIC- AND SPECIFIC-LEVEL USE

Starting in the interconnection between the key drivers and hindrances in the developing and using settings, the schematic Figure 8 shows that key drivers of the scientific development are closely interlinked to both systemic- and specific-level use, however in slightly different ways, to which we shall soon return. The key drivers in the technological development is only interlinked to drivers at a specific-level of use.

This study has distinguished between two different kinds of developments: technological and scientific. From the interfaces underlying the activities between ProstaLund–Kalmar, ProstaLund–USÖ, there is a technically oriented development, where the main incentives behind the development was to improve the treatment efficiency of BPH in medical practice. The development at Uppsala Akademiska contained fewer technological interfaces as the main purpose was to conduct research rather than to use PLFT in regular BPH

treatment. The incentives behind technological and scientific development are different so that disparate features of the PLFT device are activated in relation to established resources in the different contexts. As a production facility, it is central to understand how PLFT will affect other treatment procedures at the clinic. As a research facility, the population of patients treated and the ability to embed the results of research into the academic community are instead prioritised features in use. Public healthcare is thus involved in both *technological* and *scientific* development activities, which represent two diverging logics to engage in development activities.

The scientific development is related to two different embedding processes in the using setting, one of which takes place within the frames of the academic community amongst physicians, discussing, interpreting and further developing the data. The other, systemic level use, strives to standardise the interpretation and create fixed parameters at a systemic level, using only a restricted part of the knowledge developed in the scientific development.

Therefore, new scientific data can reach practice through central regulations after 'being filtered' through the systemic level steering tools. Nevertheless, scientific data simultaneously 'travels' through the medical academic community and physicians (all hospitals in this study included) are engaged in continuous discussions of new scientific findings, in their established treatment procedures as well as for completely new methods. Central documents can be a support in these continuous discussions and development activities at the clinics, but is not an exclusive element for integrating scientific knowledge into practice.

For the using setting, it was already established that there is an interconnection between the systemic and specific level hindrances. Moreover, the systemic hindrances create imprints at a specific level. The hindrances are of the same character at both systemic and specific level use, however underpinned by different resource interfaces. The drivers in the using setting were found at a specific level of use only but more importantly the specific level drivers were found to be entirely disconnected from the systemic level. *The fact that the key drivers to embed the PLFT device are disconnected from the systemic level regulations should thus not be equated with 'non-scientific' use*. The clinic at Kalmar hospital certainly has adapted to new scientific results in the development of the PLFT device, the main difference is that they use scientific data as embedded into an academic community, rather than a regulatory and assumingly 'objective scientific measure'. As was argued in the theoretical

chapter, the use of scientific research is context dependent. For example, there was little consensus among urologists about the efficiency of the TUMT and PLFT method, regardless of substantial scientific studies supporting its usefulness. Whereas in the academic community, research results are subject to a continuous professional debate and further development, i.e., seldom static. Therefore, the specific level drivers in the using setting are disconnected from the systemic level, but not from the scientific aspects of using the device.

Scientific data plays a significant role in creating regulations and steering tools at the systemic level. Any new device, at some point in time, has to be embedded into an academic usage context capable of establishing its scientific value before it can be subjected to assessments at a systemic level. It does not mean that the features developed during the technological development are 'lost' or irrelevant in the academic context, after all, these two processes are intermingled. Nevertheless, features and knowledge about the technology's ability as a production facility are not as significant in the scientific development where the device is embedded as a "research facility". For example, the scientific development of PLFT at Akademiska was found to neither be related to specific needs in practice nor to financial aspects of using the device in the provision of healthcare services. Whereas the key drivers in the technological development are related to specific level use only.

The technological development is practice-based and characterised by close interaction in the Public–Private interface. Here, context specific resource interfaces of both social and material character are developed. Despite the fact that these specific interfaces vary between hospitals, the technological development generates knowledge of crucial relevance to the embedding of the TUMT/PLFT device into medical practice. It is within the frames of technological development that the underlying resource structures in the provision of healthcare services become visible, e.g., overlapping treatment alternatives, education of health personnel, budgeting, internal billing systems, reimbursement structures, etc. are disclosed during technological development. The simple reason is that the incentives behind technological development exist to solve a 'close to practice problem': enhance the efficiency/lower the costs of BPH treatment. The new social and material resources and new interfaces that evolved during the technological development of TUMT/PLFT make part of that practical 'problem-solving' and should be regarded as an investment providing and preparing for future regular use.

The central resources developed in the technological development, in the public–private interface, are lost in the using setting. Scientific develop-

ment is not correlated with successful embedding into regular use, nevertheless the scientific development, let alone, is the basis for the systemic decisions of what methods shall be brought into use in the public healthcare system.

HOW THE KEY DRIVERS IN THE PRODUCING SETTING RELATE TO THE KEY DRIVERS AND HINDRANCES IN THE DEVELOPING AND USING SETTINGS

The producing setting was involved in open interaction with healthcare during the technological development. The decisions to scale up production and make further and large investments in the producing setting were based on previous interactions with the direct users, that is, medical practice. The drivers to the innovation process and establishment of a larger company has direct interconnection with the practice-based technological development and the device's usefulness in the provision of healthcare services. The scientific development is indeed an important factor to the producing setting in that it provides possibilities of diffusion in the system in general, however, the interaction in the public–private interface was less profound during the scientific development. Therefore, the key drivers in the producing setting are mainly based on the previous public–private interactions in the technological development of the TUMT/PLFT device. The key drivers in the producing setting can further be related to key drivers in the using setting at a specific level. Despite the fact that ProstaLund was faced with a highly formalised interface in the using setting, towards purchasers rather than practice, their previous established knowledge about their users builds on norms represented by the key drivers at a specific level of use.

The systemic level of use is outside of the producer's reach; there are no significant interactions, and very few to no activities they can contribute to, except for very formalised data sharing. Systemic use takes place outside technological development, the producing setting and the specific level use and has a severe negative impact on the innovation process as whole, since it is disconnected from, or counteracts, the key drivers in technological development, the producing setting and specific level use.

A SUMMARIZING COMMENT

Applying the three empirical settings of developing, producing and using has given the opportunity to get a comprehensive picture of the interrelation of key drivers and hindrances over the innovation process as a whole. A fundamental finding is that hindrances and drivers of the innovation process are

strongly related to the preconditions of each setting. The imbalanced distribution of hindrances and drivers over the settings is not intrinsic to the specific resources of the innovation process itself but rather a consequence of the underlying regulations and mechanisms of each setting. Therefore, capturing the drivers and hindrances in each setting features the complexities behind innovation processes in that the very same drivers can have different effects on the innovation process depending on the setting.

Another interesting finding from this specific case is that the system level seems to have a preferential right of interpreting scientific data, despite the very narrow and specific view applied. Medical practice on the other hand both produce and use scientific data to improve their operations in the provision of healthcare services, however to do so efficiently they have to be disconnected from the organisational norms and regulations enforced at a systemic level. Consequently, it is significant to understand the mechanisms behind scientific assessments and what information they contribute to embedding a new device into medical practice. The assessments undertaken by central authorities provides a narrow perspective and only includes a small part of the scientifically developed data, which is certainly not insignificant, but at the same time it might not provide enough information to take important decisions on the value of new methods in practice. Very little of the crucial knowledge available through technological development is acknowledge by the systemic level. There is potentially a large bulk of investments and crucial knowledge embedded into the clinics involved in technological development and not at least in the *producer*, which is not acknowledged in the using setting.

The technological development is not only an equally important platform as scientific development to the growth of new medical solutions, but a source of successful embedding into regular use in the provision of healthcare services. Also, acknowledging the different forms of development and grasping their different underlying incentives is potentially important to fully supporting the growth of new solutions within the Swedish healthcare system. Consequently, technological and scientific development might be due to diverging social contexts and incentives, but are of equal importance to the innovation process as a means to improve and aid the embedding of new solutions into regular use in the public healthcare system.

10. CONCLUDING REMARKS & CONTRIBUTIONS

This thesis initiated by asking a more general question about microwave technology in the treatment of BPH: *"What happened to TUMT and why is it that something so seemingly promising encountered such difficulties in becoming a widespread technology in the Swedish healthcare system?*".

We have seen that, despite the fact that the PLFT device was user-driven and developed in interaction between users and producers, it had significant problems becoming embedded into regular use. The case seems to contradict the key message on user involvement as conductive to innovation by, e.g., Von Hippel (1986, 1983) or Rosenberg (1981). How can we comprehend such puzzle?

This study is based on an interactive perspective, stating that innovation is an interactive and context dependent phenomenon. Interaction and the embedding of a new solution in to the settings of developing, producing and using has thus been the fundamental stances underlying the investigation of this med-tech innovation process. The findings from the case show that *interaction* was enabled and supported in the developing and producing setting, whereas in the using setting, all possibilities to interact were neglected or actually even prohibited by, for instance, legislation on public procurement. If interaction is neglected it will be very arduous to embed a new solution into regular use due to the lack of possibilities of adaptation, even though, *not impossible*. It just requires *other* conditions, namely a massive mobilisation of resources in order to *push through change*. When interaction is not allowed, expanding the use of new med-tech devices in public healthcare require a mobilisation of resources that has to be large enough to handle all of the multilevel hindrances and complexities that have been identified in this study. Thus, leaving med-tech providers and public healthcare with a nearly incomprehensibly grand task when striving to embed new solutions into use.

What this study reveal is that the microwave technology had vast support in both development and production, both in terms of possibilities to inter-organisational interaction and in terms of financial support from private and public actors (innovation agencies and public healthcare funding), without which the microwave technology would not have survived either development or production. Meanwhile, in the using setting, it did not receive much support from public actors. A primary reason for the lack of explicit public support in the using setting is that healthcare *and* innovation policy assumes that new solutions have an intrinsic value *in use*, which builds on the assumption that resources are homogenous and their value can be de-contextualised. Use is indeed regarded as unproblematic and should be taken care of by the very abstract idea of a market that is self-regulating. However, this assumption becomes especially problematic in a public healthcare context, which can be understood as anything but a market. This is a closed system of users, based on a restricted amount of financial means: tax income. This system will neither 'take care of use' by self-selecting the optimal new technologies nor will the actors (hospitals) go out of business if they are inefficient in their selections. The companies, however, will go out of business, if they fail to commercialise their products and earn profits.

In addition, the very same policy assumptions lie beneath the systemic assessment of the utility of new devices. What is regarded as 'knowledge' at a central level (data derived from health economic assessments) has become a concept encapsulated by an atomistic view of scientific medical data as true and objective, so that the knowledge management of public healthcare mirrors the very fundaments of the system; efficiency as large-scale rational processes, resources as atomistic, healthcare as one large homogeneous user of medical devices, all resting on the central stance of competition, the core mechanism to achieve efficiency.

Conclusively, if innovation actually is the goal, use cannot be excluded, the using setting to an equal extent as the developing and producing settings, needs support in terms of possibilities to interact and adapt and to achieve change in large and rigid organisational structures.

Policy implications:

The policy model is assumed to a) enhance efficiency in public healthcare and b) generate new cutting-edge high-tech devices and a thriving business climate. This study has shown that the ways in which the organisation of healthcare and its underlying control tools affects the use of new med-tech

solutions is important, because it can bring about major negative impact on new technology use or is at best never neutral against it.

First, if policy strives to support med-tech innovation with the aim of achieving a thriving business climate, it is possibly fruitful to understand the actual economic activities underlying innovation processes, i.e., interaction as observed in the business landscape, as opposed to those mechanisms depicted in models of the market (economics). Lessons from the business landscape and this case underlines the importance of interaction both within and outside the organisational boarders of public healthcare, in all of the settings: developing, producing and using. Second, if new medical devices do not achieve widespread use, companies will not be able to produce them or survive. *Use* is pivotal to any innovation attempts, and since almost all users of medical technologies are public, it is even more astonishing that use is so poorly supported within the public healthcare system. To include the direct users and producers to a larger extent, not only in the development setting but also in the using setting, could potentially have beneficial effects on 'efficient' use of new solutions. The persons in charge at a specific using unit have the best knowledge of how to combine and thus economise upon current and new resources.

Contributions to theory:
This study builds on numerous studies that have considered the complexities of medical technology innovation. Most of the drivers and hindrances that have been identified in the analysis are aligned with previous findings taken separately. However, an interactive perspective (Håkansson & Waluszewski, 2002, 2007) has aided this study to investigate interconnections over organisational borders, hence the impact of different contexts in the med-tech innovation process, as well as how several resource interfaces are interrelated and affect this specific innovation process by numerous drivers and hindrances.

In the introduction, Fitzgerald et al., (2005) were cited, in their review on innovation in healthcare the authors concluded that:

"The separation of the discussions on creating new knowledge, diffusion of knowledge and innovations and knowledge management means that interconnections between the key influences remains unclear" (Fitzgerald et al. 2005 pp.1433-34).

First, an interactive lens made it possible to identify even more closely the heterogeneity of the single clinical use context, thereby stressing the different levels and forms of localised use, all requiring some degree of local adaptations and investments involving highly heterogeneous resources. Furthermore, capturing these interaction patterns over the three settings of developing, producing and using, has shown that the very same actor, namely public healthcare, will change its interacting capabilities, depending on which of the three settings is considered. As a developer, public healthcare embeds resources in a way that is similar to the interaction patterns observed in the business landscape. Whereas in a using setting, public healthcare economises on resources through a logic, other than the one typical of the business landscape, namely a logic whereby users are constrained in the interaction with other external organisations, especially private ones.

Second, this specific case shows that *financial incentives* and not necessarily 'practical needs' can trigger the development of new devices and simultaneously hamper the embedding of new devices into regular use. In development, we have noticed a bottom-up approach, without any initial correlation to scientific medical research. Even if the practice-based medical innovation is common currency, the 'rational procedure logic' entrenching and triggering this development from the beginning may not be. That the microwave device by all means should be able to replace surgery, before development had even started, is potentially an interesting development mechanism that points to the permeating force of the 'financial' and large-scale perspective in healthcare. The financial perspective was, in this development, a mechanism as important as any other 'purely medical' incentive to develop a new device. In the using setting the financial perspective was found to be equally dominating, yet creating opposite effect from the developing setting. The fact that the financial perspective to such large extent dominates the organisation of healthcare, makes other perspectives, such as the professional caregivers and the patients, less significant. Instead, the system levels' very specific view of efficiency, as depicted in economic models and large-scale logic with a strong financial focus, have become the norm for efficient organisation.

Third, Systemic aspects push for scientific development that shall establish the value of using new technology at a national level. Yet, from this case comes out that embedding into regular use only took place where drivers were *disconnected* from the systemic level and where decisions to use the device were based on localised practice-specific assessments.

Fourth, the multiple context perspective has given an insight to how imbalanced the med-tech innovation process appears to be. The distribution of drivers and hindrances is far from even with regard to the settings, leading to the conclusion that support should be evenly allocated to the settings, given that they are of equal importance to achieve innovation.

Further research:
It would be of interest to further investigate the scope of public support both in development and when ready to be introduced into regular use. It could be investigated which hindrance large med-tech companies meet in their innovation process and if they have an advantage over very small businesses that are probably less able to mobilise sufficient resources for their innovations and embed them in the public system. Such a further study should verify if healthcare actually affects the performance or even the survival of small to medium-sized companies by making it difficult for them to entrench their innovations in the healthcare system due to limited resources.

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Patent

US4967765A
https://www.google.com/patents/US4967765 (2016-09-01)
inventors; Turner Paul F, Schaefermeyer, Tumer, Nguyen, 6 november 1990

APPENDIX I

	Informants	Titel	Date	Form of interview
PROSTALUND				
1	Magnus Bolmsjö	CEO ProstaLund	03-06-10	Mail Interview
2	Lennart Wagrell	Chief physician, Urologcentrum	04-10-22	Interview
3	Magnus Bolmsjö	CEO ProstaLund	05-06-28	Interview
4	Mikael Flensburg	Sales director ProstaLund	05-09-23	Interview
5	Carolina Pancarz	Sales Manager ProstaLund	05-09-23	Interview
6	Jan-Erik Nilsson	Production and Logistics manager ProstaLund	05-09-23	Interview
7	Carolina Pancarz	Sales Manager ProstaLund	06-01-18	Mail Interview
8	Lennart Wagrell	Urologist	05-09-28	Interview
9	Ulf Rosén	CEO ProstaLund Operations AB	08-01-25	Interview
10	Magnus Bolmsjö	CEO ProstaLund	06-09-22	Interview
11	Ulf Rosén	CEO ProstaLund Operations AB	09-02-11	Interview
12	Magnus Bolmsjö	Former CEO ProstaLund	10-01-25	Telephone interview
UPPSALA AKADEMISKA UNIVERSITY HOSPITAL & PURCHASING ORGANISATION				
13	Christina Södergren	Chief executive of Uppsala county purchasing depart-ment	05-12-08	Interview

14	Johan Berndes	Purchasing manager Uppsala County purchasing department	05-12-08	Interview
15	Mikael Häggman	Physician, Urology department Uppsala Akademiska Hospital	05-12-08	Interview
16	Christina Södergren	Chief executive of Uppsala county purchasing department	06-07-07	Telephone interview
17	Mikael Häggman	Head of Urology department Uppsala Akademiska Hospital, MD Urology	06-11-04	Interview
18	Lennart Wagrell	Urologist former employee at Uppsala Akademiska urology department, MD of Urology	07-02-21	Interview
19	Bo-Johan Norlén	Former head of Urology department at Uppsala Akademiska Hospital, Professor emeritus Urology	07-02-23	Interview
20	Mikael Häggman	Head of Urology department Uppsala Akademiska Hospital, MD Urology	07-02-26	Interview
21	Eva Johansson	Physician, Urology department Uppsala Akademiska Hospital	07-02-26	Interview
22	Ulf Haglund	Director of research at Uppsala Akademiska Hospital	07-08-31	Interview

23	Brita Vinsa	Director of Neurology division at Uppsala Akademiska Hospital	07-09-13	Interview
24	Margareta Tufvesson	CFO Uppsala Akademiska Hospital	07-10-23	Interview
25	Sonja Ekström-Boström	Head of department for premises	07-12-21	Interview
26	Marie Beckman-Suurküla	CEO Uppsala Akademiska Hospital	07-12-04	Interview
27	Margareta Tufvesson	CFO Uppsala Akademiska Hospital	08-03-05	Mail Interview
Örebro University Hospital (USÖ)				
28	Jörgen Pedersen	Former Head of urology department, Örebro University hospital	07-02-05	Interview
29	Malcolm Carringer	Chief physician, Urology department, Örebro University Hospital	07-08-03	Interview
30	Gustav Ekbäck	Director of surgery division, Örebro Univesrity Hospital	07-10-03	Interview
31	Lennart Frommegård	CFO, Örebro University Hospital	07-10-03	Interview
32	Carina Lindskog	Director of healthcare development, Örebro University Hospital	07-10-08	Interview
33	Tore Öberg	CEO Örebro University Hospital	07-10-08	Interview
34	Malcolm Carringer	Head of Urology department, Örebro University Hospital	08-02-07	Telphone and mail interview
Lund University Hospital				

35	Eva Broström (a)	Head of Urology department, Lund University Hospital	10-02-10	Interview
36	Lars Malmberg (a)	Chief urologist, Lund University hospital	10-02-10	Interview
37	Bent Christensen	CEO Skåne University Hospital (SUS)	09-09-17	Interview
38	Håkan Cederholm (a)	CFO Skåne University Hospital(SUS)	10-06-17	Telephone interview
39	Lars Malmberg (b)	Chief urologist, Lund University hospital	10-11-19	Mail Interview
40	Eva Broström (b)	Head of Urology department, Lund University Hospital	10-11-17	Telephone interview
41	Håkan Cederholm (b)	CFO Skåne University Hospital(SUS)	10-08-20	Mail interview
Kalmar Regional Hospital				
42	Sonny Schelin	Physician Urologist, former chief urologist at Kalmar regional Hospital	09-02-19	Interview
43	Lennart Wagrell	Physician, former employee at Kalmar regional hospital	10-10-18	Interview
44	Elisabeth Palmqvist	Urologist Kalmar Regional Hospital	10-11-27	Telephone interview
45	Jonas Rastad	CEO Kalmar Regional Hospital	10-06-03	Telephone interview
46	Sonny Schelin	Physician Urologist, former chief urologist at Kalmar regional	10-05-31	Telephone interview
47	Elisabeth Palmqvist	Former Urologist Kalmar Regional hospital	13-09-23	Mail interview

DOCTORAL THESES

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