



LUND UNIVERSITY
School of Economics and Management

Is Health Technology Assessment a part of the
purchasing process for inpatient care?
A survey study in Sweden for MDD products

Author: Emma Lund

Supervisor: Professor Carl Hampus Lyttkens

Department of Economics

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Introductory remark

I want to thank Anna Lefevre Skjöldebrand, CEO of Swedish Medtech, for the trust of allowing me to conduct this survey for them. I also want to thank Petrus Laestadius, Sofia Medin and Malin Hollmark at Swedish Medtech for the support and encouragement. I am grateful for my thesis supervisor Professor Carl Hampus Lyttkens for helping me stay on track.

Abstract

The purpose of this report is to map how HTA, Health Technology Assessment, is being used for MDD products for inpatient care in Sweden. Swedish Medtech, a professional association for medical technology companies, has a need to carry out a survey about the use of HTA in Sweden for their future work. They have a project which goal is to inform policy makers about the value of innovative medical products and treatment, where HTA can be one way of informing about the value. As a starting point in Swedish Medtech's project, this mapping shows today's situation.

For Sweden to have an evidence based care, there are numerous health economic evaluation approaches. HTA goes deeper by using academic literature, ethical and social aspects together with health economics to analyse methods for health care. HTA analysis aims to answer the question: is the benefit of the method worth the cost?

The conclusion from this report is that HTA is used today, but only in limited extent in the three biggest healthcare providers. This report has not found any specific pattern on the use of HTA with the restrictions in this paper.

Key words: Health Technology Assessment, MDD products, Swedish Healthcare, Public Procurement, Inpatient Care

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Abbreviations

DRG	Diagnos relaterad grupp kod
HTA	Health Technology Assessment
INAHTA	The International Network of Agencies for Health Technology Assessment
LOU	Lagen om offentlig upphandling (the Public Procurement Act)
MD	Medical Doctor
MDD	Medical Device Directive
MPA	Medical Products Agency
NICE	The National Institute for Health and Clinical Excellence
SBU	Statens beredning för medicinsk och social utvärdering, (Swedish Agency for Health Technology Assessment and Assessment of Social Services)
SLL	Stockholms läns landsting (Stockholm County Council)
TLV	Tandvårds- och läkemedelsförmånsverket (The Dental and Pharmaceutical Benefits Agency)
VGR	Västra Götaland Regionen (Västra Götaland Region)

1. Introduction

In Swedish health care, the medical doctors and nurses are obligated to work according to science and proven knowledge. At the same time, estimates show that more than 1.4 million medical articles are published each year which give the individual caregiver an impossible task: to keep up with the ever-growing stream of new information (SBU, 2014). The vast number of research results needs to be reviewed, sorted and compiled to become more transparent. Health Technology Assessment, HTA, is a report of academic background for a specific method and can be of help for evidence based decision making (Drummond, et al., 2008).

Introduction of new methods are often expensive in health care which also means that there is an increased pressure of proven effectiveness when introducing new methods. This has resulted in an increased focus of economical evaluations and HTA for the evidence based care. An economic evaluation means that two or more treatments are compared by the costs and health effects, which becomes a valuable analysis for decisions on effective use of health care resources (Drummond, et al., 2015). HTA as a policy tool is used in developed countries' health care which started in the 1970s in the USA (Zethraeus, 2009). HTA reports from NICE, The National Institute for Health and Clinical Excellence, is used as a base for recommendations in health care in England and Wales (NICE, 2013). Australia and Canada were the first to have cost-efficiency as a requirement for decisions on reimbursement of medicines (Zethraeus, 2009). In Sweden, HTA has been used since 2002 as a standard for the national benefit schemes of drugs decided by TLV, The Dental and Pharmaceutical Benefits Agency (Mehmood Birchall Shah, et al., 2014).

One should know that the pharmacy industry and the medical technology industry differ both with legislation and practise. The pharmacy industry is regulated and controlled by Medical Products Agency, MPA, that approves drugs for the Sweden market (Medical Products Agency, 2014). TLV approves which product are subsidised for outpatient care (The Dental and Pharmaceutical Benefits Agency, 2014). Normally, the medical products are purchased on the county council, region or hospital level.

HTA is also growing internationally in terms of collaboration with the idea to benefit from cooperation and to avoid duplication as well as to share information between HTA organisations. To mention a few, in 1993 the International Network of Agencies for

Health Technology Assessment, INAHTA, took form and is a network of 52 HTA agencies in 32 countries (INAHTA, 2016). In 2006 the European network for HTA, EUnetHTA, was founded after the European Commissions and Council of Ministers made HTA a political priority (EUnetHTA, n.d.a).

Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU, makes systematic reviews of the best available scientific evidence in order to evaluate and apply new methods in healthcare. During the last decade, County Councils and Regions have started to build up their own local HTA organisations to analyse the county council's health care (SBU, n.d.a).

There are numerous initiatives to standardise the context of HTA and various definitions of the report (Draborg, et al., 2005). They all recognise that HTA is an important decision making tool, that should be multidisciplinary and have a strong transparent method as base. As mentioned, one part of the HTA is economic evaluation and the different definitions of HTA which has similarities within them. It should be noted that the perspective of the evaluation can differ from healthcare perspective to a societal perspective (Zethraeus, 2009).

This paper will use the definition of HTA according to SBU, which is that the report should include previous academic results, health economics, social and ethical aspects (SBU, 2014).

This trend of HTA use for pharmaceutical products has, however, not been followed in the medical technology field where this paper has its focus. Although HTA has a long history, the structure of using and implementing the results from a HTA is still growing which gives this paper its main purpose: mapping the use of HTA on MDD products for inpatient care. This paper has a secondary purpose, which is to give a foundation to Swedish Medtech's future work of how to evaluate medical technology with the use of HTA.

2. Goal of research

The purpose of this paper is to get an overview where and how HTA, Health Technology Assessments, is being used in Sweden for medical technology products at inpatient care. It will investigate how purchasing organisations take HTA into consideration when buying MDD products. This positive research aims to give a foundation for future assessments of HTA use in Sweden.

It is logical to assume that a region with a local HTA organisation might be more familiar with the concept and use it, therefore this report will analyse regions in Sweden with their own HTA organisations.

2.1 Research questions

Is there a pattern for where and how many HTAs are being used for MDD products at inpatient care?

The following question will be analysed as sub-question in this paper. When is HTA not used and why?

2.2 Hypothesis

I assume that HTA is used when there is new innovative technology that has an extensive influence on methods, is costly for the producer or has a big impact on the budget for the hospital.

This is due to that the seller will have an incentive to prove that their new technology is better and more cost effective than today's method and therefore use HTA as a selling argument. The hospital, on the other hand, will have an incentive to use HTA for purchasing MDD when it is of economic importance or has methodology effectiveness to gain.

3. Theoretical background

In this section, definitions of HTA reports, MDD products, public procurement rule, purchasing process for inpatient care, overview on the administrative authorities in Sweden and the Swedish County Councils and Regions will be explained.

3.1 HTA

As mentioned, there are several definitions of HTA.

The International Network of Agencies for Health Technology Assessment defined HTA as: “an intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. Health technologies include pharmaceuticals, devices, procedures and organizational systems used in health care” (INAHTA, 2016).

EUnetHTA defines HTA as “a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value” (EUnetHTA, n.d.b).

SBU defines HTA as a systematic evaluation of a specific method’s medical, economical, ethical and social effects (SBU, 2014).

As stated in the introduction, HTA is created to give an evidence based care. It can be applied as a basis for the revision of existing medical technology and monitoring current methods. HTA is a way to choose method where decisions are built on the best available scientific data and best practice in cooperation to maximise the utility of the Swedish krona spent on health care in combination with soft values like quality of life, etc.

In a HTA-report, the new technology is often compared with the method used in today’s health care and it should be conducted in a multidisciplinary nature. The perspective of economical evaluation in a HTA can differ and TLV recommends the societal perspective (International Society for Pharmacoeconomics and Outcomes Research, 2013). This means that the costs outside the hospital should be included. According to SBU’s guidebook, they also recommend using the societal perspective for HTA and emphasises

that it can be of interest to calculate how the method might affect different budgets (SBU, 2014). But generally, the perspective is often taken from the health and medical care (Zethraeus, 2009). This paper will use SBU's definition of HTA since it is the one referred to by the county councils and regions in Sweden.

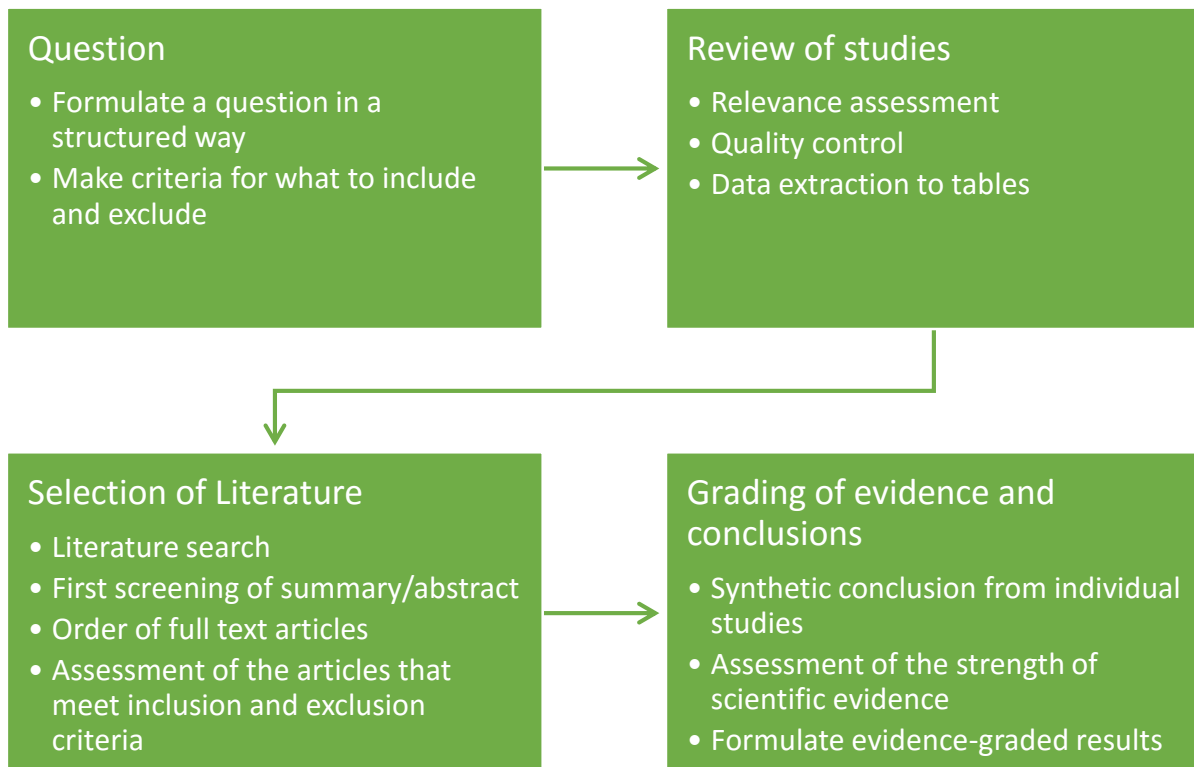


Figure 1. SBU's method for a HTA report (SBU, 2014)

HTA can be a valuable tool for making health care more efficient but there must be more research made on the field of HTA use for medical technologies (Sorenson, et al., 2008). The decentralized health-care system in Sweden makes it difficult to measure causation and impact of HTA on a local level. On a national level, there are findings that shows that certain HTA reports have had an impact on guidelines and clinical practice (Britton & Jonsson, 2002).

3.2 MDD

Europe has a comprehensive legislation specifying the requirements of the medical devices placed on the market. The basis for this regulation is the Act (1993: 584) concerning medical devices and the regulations published by the Medical Products Agency. The definition of a medical device can be found in § 2 law on medical devices (Medical Products Agency, 2006).

In this paper the definition of medical technology according to EU standards MDD, Medical Device Directive, will be used. It is a classification to ensure that the products placed on the market are safe and fit for its purpose (Consumer Affaris, 2010). Hence, the aim is to prevent accidents and incidents by imposing requirements on the products and those who place products on the market (Medical Products Agency, 2006). Therefore, when writing MDD product, it means medical technology products according to EU's legislation.

3.3 The Public Procurement Rules

The Public Procurement Rules was created to ensure that contracting authorities use public money to finance public purchases in the most beneficial way (Swedish Competition Authority, n.d). The aim of the Public Procurement rule is also to promote free movement within the EU, eliminate practices that restrict competition, make it easier for companies to do business with the public sector and to ensure that the company offering the goods that fulfils the requirements and has the most favourable terms wins (The National Agency for Public Procurement, n.d).

Public procurement is controlled by the Swedish Public Procurement Act (2007:1091 – LOU), which have a foundation in the EU Directive concerning public procurement (Swedish Competition Authority, n.d).

Since 2015 Sweden has a new institution, the National Agency for Public Procurement, which purpose is to support the procurement conducted by contracting authorities and entities. This organisation's task is to provide support and practical guide lines to make the public procurements more efficient. (The National Agency for Public Procurement, n.d)

The Swedish Public Procurement Act have five fundamental principles that must be followed at all times:

3.3.1 The principle of non-discrimination

This principle is formed in the way that it is prohibited to discriminate suppliers based on nationality. Discrimination is not allowed directly or indirectly.

3.3.2 The principle of equal treatment

This principle highlights that all suppliers have to be treated in the same way. As a result, it is mandatory that all suppliers must have the same information at the same time.

3.3.3 The principle of transparency

It means that the purchaser has to have a transparent procurement process, give information about the procedure and how it will be conducted. Information regarding the procurement may not be kept secret and the procurement should be advertised publicly. It is important that the contract documents must be distinct and include all the requirements for the subject matter. Therefore, the suppliers will have the opportunity to know the specifications. The vendors who participated in the tender procedure should be informed of the outcome.

3.3.4 The principle of proportionality

It means that requirements in the specification have to have a clear link as well as be proportionate in relation with the subject of the contract.

3.3.5 The principle of mutual recognition

This principle highlights that all EU and EEA countries have to accept certificates and diplomas issued by authorities authorised by a Member State

3.4 Purchasing process for inpatient care

For the MDD products, when procurement is being made, the purchasing organisation and the tenderer are obliged to follow the Public Procurement act among other laws (Swedish Competition Authority, n.d). The purchasing part can either be the hospital or the county council. In some cases, also wholesale organisations are being used.

Generally, since the county council is responsible for the health care in the county, they usually make the purchase. If the need for the goods are relatively small or hospital specific, the hospital can themselves act as purchaser.

The regions and county councils have similar procurement processes. As an example, the procedure for a procurement in Region Skåne is the following:

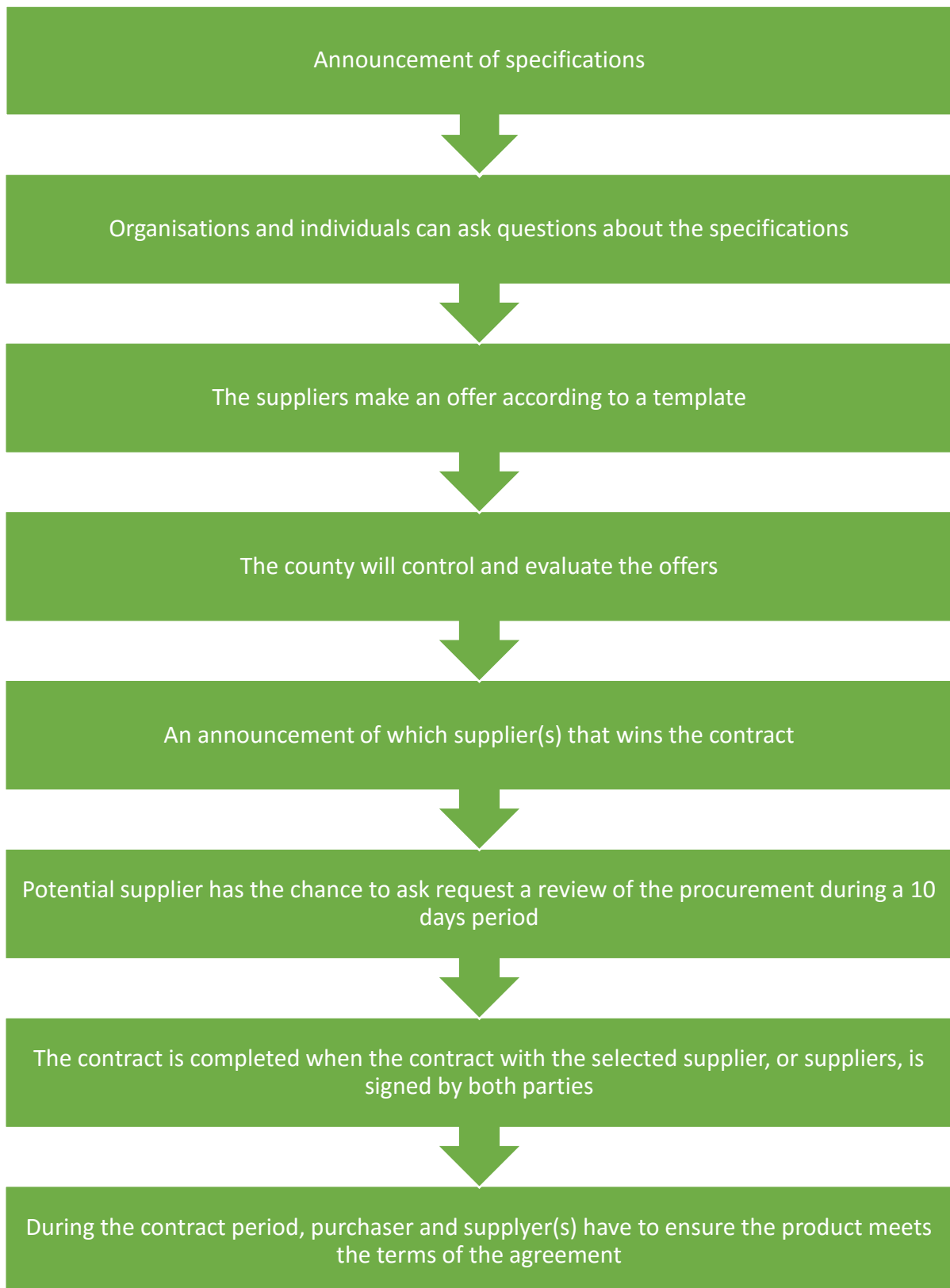


Figure 2. The procurement process in short according in Region Skåne (Region Skåne, 2016)

3.4.1 Advertising of specifications

They publically display their specifications on a website.

3.4.2 Questions about the documentation

When the specifications are published, anyone can ask questions about the content of the documents. Since all suppliers should have the same opportunity to submit a competitive bid, they will publish the answers, clarifications and additions simultaneously.

3.4.3 Tender Presentation

When a supplier designing its bid, it is important to check that all the questions have been answered and submit all documents requested in the tender documents. To miss to attach a document that has been requested may result in exclusion from the tender.

3.4.4 Tender Consideration

After the tender period the region or county council will evaluate the received bids. They verify that the supplier meets the requirements of the product or service, that all questions are answered and that the requested documents are filed with the content requested. Tenders will be evaluated based on the requirements in the specification.

3.4.5 Contract award decision

The tender that won will be announced via the contract award decision. The basis for the award decision that the evaluation model and in some cases is the lowest tendered price and in some of the most economically advantageous tender. Depending on how the contract is formed, it can be one or more tenderers to whom the contract award decision.

3.4.6 Standstill period

During the 10 days of the contract award decision, any supplier have the chance to ask for a review of the procurement.

3.4.7 Enter into agreements

The contract is completed when the contract with the selected supplier, or suppliers, is signed by both parties.

3.4.8 Agreement Monitoring

During the contract period, the county council or region meet their suppliers to have a dialogue on how the work to ensure that it meets the terms of the agreement. Experience from contract monitoring is important for future procurements.

3.5 Overview on the administrative authorities in Sweden

Sweden has one of the longest histories in the world when it comes to conducting HTA analysis (Jonsson & Banta, 1994). To make it more clear which institutions that works with HTA, the following is a brief summation of their main tasks.

Administrative authority	Main tasks
Medical Products Agency, MPA (Läkemedelsverket)	Decision of medical approval. Focus on effect and safety.
The Dental and Pharmaceutical Benefits Agency, TLV (Tandvårds- och läkemedelsförmånsverket)	Decision of subventions for medical products and dental care. Focus on cost effectiveness.
Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU (Statens beredning för medicinsk och social utvärdering)	Responsibility for systematic reviews and evaluation of methods in health care.
The National Board of Health and Welfare (Socialstyrelsen)	Responsibility for national guidelines, regulations, register and more.

Figure 3. Responsibilities between healthcare authorities in Sweden (SBU, 2014)

The Medical Products Agency's obligations are regulating and supervising the development, manufacturing and sale of medicinal products (Medical Products Agency, 2014). They also authorize and supervise the pharmacy business in Sweden.

TLV's main responsibilities are deciding subventions for medicinal products, medical devices and dental care (The Dental and Pharmaceutical Benefits Agency, 2014). They also conduct health economic assessments for decision makers in the health care (The Dental and Pharmaceutical Benefits Agency, 2016).

SBU, Swedish agency for health technology assessment and assessment of social services, is the world's oldest HTA organisation and was founded in 1987 (SBU, 2014). Their main task is to systematically gather literature and evaluate medical methods. This means that SBU compile scientific knowledge about the effectiveness and cost-effectiveness of various methods. They conduct a vast number of HTAs which are independent published

scientific evidence. Therefore, SBU do not make evaluations either on behalf of or in collaboration with specific companies (SBU, n.d.b).

SBU priorities topics for nominations based on two steps. First, by scanning different fields of interest and conducting a topic list for discussion by SBU executive committee and project coordinators (Carlsson, 2004). Second, a list is made and presented to the SBU board of proposals and selections of pilot studies. It is the SBU Board that make the final decision for conducting a HTA analysis based on following criteria (Carlsson, 2004).

- There must be sufficient data for the topic.
- The topic must have a significant effect on health in terms of, mortality and morbidity.
- The topic must relate to the breadth of health problem.
- The topic may have a societal and ethical consideration or of big concern to the broader public.
- The perceived importance of the topic should be demonstrable from an organisational or professional standpoint.
- Methodical requirements.
- Technology cost.
- Relevance for technology.

The National Board of Health and Welfare have a vast number of responsibilities. Among them are conducting national guidelines, regulations, registers, examine and issue legitimations for staff in various professions and more (Socialstyrelsen, n.d).

All these four organisations are important to Swedish continues development of medical care, and this paper will mainly focus on SBU's work since their responsibility is to evaluate methods for this industry.

3.6 Swedish County Councils and Regions

The county councils and regions in Sweden are responsible for tasks that are common to large geographical areas and often requires large financial resources, among this, is the health care (Sveriges Kommuner och Landsting, 2015). To make this report clear, a county is the geographical area and the county council is the administrative organisation

governing area. Latest years, some County Councils have adapted the form of Region (Sveriges Kommuner och Landsting, n.d).

Today, there are five HTA local organisations within county councils and regions in Sweden. Örebro County, Västra Götaland County, Stockholm County where Region Gotland also belongs for the medical purchase, Sydöstra Sjukvårdsregionen and Region Skåne (SBU, n.d.a). Individuals working with health care and that lives within the county council or region can give suggestions to the local HTA organisation what the next HTA analyses should be about.

Out of these five, the three biggest purchasing parties are Stockholm county council with Region Gotland, Region Skåne and Västra Götaland Region (SCB, n.d). The estimated population living in these areas is calculated to 5,241,139 out of 9,851,017 in December 31st, 2015 (SCB, n.d).

3.6.1 HTA organisation in Region Skåne

Region Skåne works in a local and regional structure. They can provide resource and methodology support for HTA to all administrations within Region Skåne working with diagnostics or treatments (Skånes universitetssjukhus, 2015). They are located at Skåne University Hospital in Malmö, which is confirmed by MD, PhD, SC Martin Laurell, Head of Skåne Regional HTA (interweaved May 25th, 2016). Generally, one project engages 2-6 people and they try to finish the report within 8-12 weeks.

The local HTA organisation conducted 3 HTA reports in 2015. None of these 3 reports were towards the MDD market (Skånes universitetssjukhus, 2015).

3.6.2 HTA organisation in Region Västra Götaland

HTA-centrum is placed at Sahlgrenska University Hospital. This HTA-centrum also conducts and is responsible for quality assurance of the HTA-projects implemented within Västra Götalands administrations (Thorin, 2014). During 2015, they published 9 HTA reports on their website where 7 of them were related to MDD products (Thorin, 2016).

Professor Christina Bergh (interview 17 May, 2016), Head of Region Västra Götaland's HTA centre, informed that to nominate a project for a HTA, the nomination has to come from someone working within Västra Götaland region, it cannot come from a producing company. The hospital or clinic that nominates have to have the approval of the

operations manager, this is due to that they have to invest some time from the health care to contribute to the HTA process.

3.6.3 HTA organisation in Stockholm County Council and Region Gotland

Stockholm County Council, SLL, work together with Region Gotland in purchasing for medical care (Felix, 2016). The local HTA unit was founded in Stockholm 2009 and is placed 10 min walk from Södersjukhuset in Stockholm. During 2015 they did not publish any HTA reports, instead they gave out 9 recommendations (Vårdgivarguiden, n.d).

4. Research Method

This report is based on information from Swedish authorities, other organisation's information from their webpages, academic articles and interviews via telephone and e-mail. In total 12 persons working directly with the purchasing process and 4 people that conducts HTA reports were interviewed.

The goal was to interview the chief procurement officer or the heads of procurement under them of each region or county council. This is due to the assumption that as responsible for the purchasing organisations they would have high knowledge where and how HTA are used within their organisations. If this was not possible, I contacted the individual purchaser or HTA managers directly.

For the interview process, the first step was to call the interviewee to get a first impression of how they use HTA. If I for some reason were unable to get in direct contact with them, then the second step was to e-mail five questions (see figure 4 for questions in English or appendix for Swedish). Since they received the questions in writing, I could not be ensured that the answers given were "first impression answers", since they had the opportunity to discuss the topic with colleagues. If anything was unclear, a follow up for better understanding were made.

The questions asked were a mix of open and closed questions, with the purpose that open questions will allow the interviewee to give a broad answer. There was a possibility that information would come up during the interviews that may not answer this thesis but can give information for future research areas. Those comments were documented.

Questiones aksed:

- Have you used HTA for public procurement of medical equipment products?
- If you have not used HTA, why not?
- Do you have a list of products that you used HTA for?
- Have the local HTA organisation or SBU reports formed the basis for any procurement?
- What would it take for you to use HTA when buying medical equipment products?

Figure 4. Questions asked during interviews

The questions in figure 4 were made in the way to answer the question in this theses: is there a pattern for where and how many HTAs that are being used for MDD products at inpatient care?

The first question is a close question, to map if HTA is being used. This question was modified depending on the interviewee, if the person asked was the head of the department, the question was if they used HTA in their department. If the person was a purchaser, the question was if he or she used HTA.

The aim of the second question was to get a motivation why HTA was not used. This is an open question to let the interviewed explain why he or she does not use HTA.

The third question's aim was to make a register on how many HTA's was used as a base for a procurement. This is since it is not mandatory for the purchaser to follow the recommendation of a HTA report. This was due to that the HTA organisations did not conduct this list themselves.

The fourth question was to find out if the HTA was from a HTA organisation. This is to get a feeling of how connected the HTA organisations are with the purchaser.

The purpose of the last question is to get a broad base for the possibilities and possible obstacles to use HTA. The question was asked openly for the interviewed to freely express their personal experience.

For selecting which part of Sweden this report should cover, I used areas with local HTA organisations. As mentioned, there are five county councils and regions in Sweden that has specific HTA-organisations within them: Stockholm county council with Region Gotland, Region Skåne and Västra Götaland Region (SBU, n.d.a). This paper will cover the three biggest purchasing parties in Sweden with a HTA-organisation: Stockholm county council with Region Gotland, Region Skåne and Västra Götaland Region (SCB, n.d). They might work as an indicator of how HTA-reports can be used. By interviewing those with HTA-organisations, it will allow a further discussion and analyse if the HTA organisations have some effect on decisions taken in that region.

Some hospitals also buy directly, but this report will focus more on the county council and regions since they purchase bigger volumes and since they are the most common buyers.

5. Results

After conducting the surveys, the overall result shows that HTA is used in some cases. However, I found that they do not use HTA in a systematic way when purchasing medical products in Stockholm County Council, Region Gotland, Region Skåne or Region Västra Götaland. None of the investigated regions or the county council document if they use the recommendations of HTA reports.

5.1 Region Skåne

The Head of Drug and Medical Technology in Region Skåne, Mr. Måns Weimarck, (interviewed April 19th, 2016) informed about the use of HTA via a telephone interview. In 2015, Region Skåne conducted 55 Public Procurements for MDD products for inpatient care. Only one of them was supported by a HTA-report. Mr. Weimarck clarifies that this small scale use of HTA is due to many things and some of the problems are different budgets within the healthcare organisation and that the Public Procurement law is written for the supplier.

In Skåne, as a general rule, the hospitals have three separate health care budgets which inhibits the process to make the whole hospital more efficient.

Examples described by Mr. Weimarck were surgical robots and distance monitoring.

“A surgical robot can cost around 20 million Swedish kronor. The benefits of using them is the healing process will be quicker, in other words, the patient will not need as many sick-days. The result from health economic calculations showed that the robots were too costly for the benefit, but Region Skåne bought these robots even though the rehabilitation will be shorter, which will not be shown in the hospital’s budget. Skåne invested in these robots since the whole society will be better off, it is just not shown in the hospitals calculation.

With new innovative technology, it is possible to monitor patients on a distance, in other words, patients do not need to physically meet the doctor in some cases. For example, the patient data can be transferred via a smartphone, which calculates drug dosage for thinning the blood instead of going to a nurse every week that has to manually measure and calculate the dosage. However, this kind of monitoring a patient on a distance is new,

and there is a need to find a system how to charge for the doctor's work. This medical technology has not yet been bought by Region Skåne."

Mr. Weimarck informs that the purchaser also has to take into consideration and comparing the costs for medical treatment or giving the patient a surgery.

The purchaser buys what the hospital asks for, however, Region Skåne has a rough and long term planning related to large purchases such as X-ray machines. In some cases, they must begin procurement 1.5 years before, so the planning and forecasting is crucial.

Mr. Weimarck mentions that they have a 3-year test period now in Ängelholm where the budget problem might not be an issue. This project is called Hälsostaden and is unique since the inpatient, outpatient and nursing homes are all under the same budget.

Mrs. Ann-Britt Karlsson (interviewed May 11th, 2016) is one of the responsible purchasers at Hälsostaden. After talking to her colleagues she concludes in an e-mail that HTA is not incorporated in their work of public procurement nor do they work with the local HTA organisation in Region Skåne.

The Head of Medical Material in the Procurement organisation for Region Skåne, Mr. Kristian Silfverberg, (interviewed May 9th, 2016) also informed by telephone that they have health economics colleagues in Region Skåne that does not work with the actual purchasing, but, the purchasers do small evaluations and try to take more than just the budget into consideration. Mr. Silfverberg made one example from 2015, when they were to buy around 300 different articles. In the tender specification, they required the tenderer to be an active supplier. In other words, Region Skåne wanted a supplier that competed on quality and services, not only with price. He mentions that this is a trend where the seller takes an active part in developing new methods to make the health care more efficient. Mr. Silfverberg comments that health economics is a very popular word, almost as an icon, but unfortunately not used to its full potential.

5.2 Region Västra Götaland

Mr. Conny Melvinsson, Purchasers for Anaesthesia and Intensive Care (interviewed April 20st, 2016), informed via telephone that he does not use HTA due to lack of incentives. He has tried to use HTA but has faced several problems; the economic structure, different

budgets arrangements which means that the cost can be on one clinics budget and the benefit in another. He also mentioned that he understands the public procurement rule to be written for the suppliers. There has been an increase in competition, which has resulted in over 4000 trails for all public procurements per year in Sweden.

Mr. Melvinsson gave two examples where a cross budget solution would be profitable for the whole hospital.

First, coming in to a hospital and get a pacemaker. In the current situation, the pacemaker is a normal one and the financial incentive is the DRG (diagnosis related group codes) that one gets paid biased upon. The technology today would allow a remotely read pacemaker. This would mean that the pacemaker can give information to the Medical Doctor, MD, without physically meet the patient. But the problem is the financial system. If one were to take the product with a remote, the MD and the hospital would be able to monitor and treat more patients, which would lead to a more efficient health care. However, there is no economic incentive to take on the product in the current situation.

Second, the technology today allows to make varicose vein surgery by laser, which means that the patient can go home the same day and avoid the cost of hospital stay. But, since the hospitals and the different units have different budgets there is a lack of incentive for the paying clinic to buy the product. Due to this system, VGR still use the old method where the patient needs to rest in the hospital and at home for weeks. During this time the patient will not work and be a cost for the society.

Mrs. Jacqueline Siegenthaler (interviewed April 21st, 2016), purchaser for Medical Supplies and Health Care explains via e-mail that the procurement process in VGR works in the way that the buyer is engaging project groups with expertise from the organisations concerned. As a purchaser, they are responsible for the commercial part of the agreement, while the project team is responsible for the expertise, clinical relevance, evidence, etc. within the procurement process. The purchaser has to rely on the outcome from the health care expertise. To implement HTA, she express that they would need to change the structure of the procurement work. From Mrs. Siegenthaler's perspective, it could be of interest to use HTA from a purchaser point of view, and more important is, that the cost carrying clinics and hospitals has to bring in such a mind set into the procurement process. She express concerns that if the initiative comes from the purchase

and procurement department, then the initiative might be understood in a negative way by the health care professionals. Therefore, this could be an issue to bring to the VGR executive group for overall guidance.

5.3 Stockholm County Council

The Head of Procurement of Medical Devices, Mrs. Anna-Karin Ahnell (interviewed April 27th, 2016), informed by e-mail that there is no specific HTA organisation for the purchasers.

Mrs. Ahnell explains that there have been several initiatives to work with HTA but they do not have a systemised way of using HTA reports within SLL. She informs that they understand the importance to incorporate HTA in the future procurement processes and that SLL is proceeding in that direction.

After discussing this with her colleagues, Mrs. Ahnell explains that for procurement of equipment, they do an evaluation based on life cycle costs, and strive to include consumption, service cost and more for the obtaining of equipment. She mentions that HTA might be used in the examination of the market and therefore might be incorporated in the product specification.

Mrs. Ahnell informs that one important aspect of last year's and this year's procurements are that there is an extraordinary number of equipments to newly built hospitals such as Nya Karolinska, new buildings at Södersjukhuset, Karolinska in Huddinge, Danderyd and Sollentuna hospital. Unfortunately, SLL does not have a register if they have used HTA reports to the above examples.

6. Discussion

This report shows that HTA is used today, but only to a limited extent. My findings are that the three biggest healthcare providers in Sweden, Stockholm County Council, Region Gotland, Region Skåne and Region Västra Götaland that represents 53.2 % of the total population in 2015, conducted 7 HTA reports concerning methods for MDD products.¹ According to Region Skåne they did 55 Medtech tenders during the same time period. If we make the assumption that Region Västra Götaland and Stockholm County Council would have the same number, we would have a total of 165 Tenders during 2015. This gives a HTA use ratio of 4,2%.²

My expectation was to find a more frequent and systematic use of HTA before and during the purchasing process.

It seems as they are 4 main factors that limits the purchasers from using HTA in the procurement process: the budget structures, the incentives, lack of knowledge and acceptance from the healthcare profession.

6.1 Budget structure

It appears that a common threshold for using HTA reports was the budget structure for the hospitals. When learning health technology by the text book, it is counted in the way that benefits the whole society, and may not include who's budget pays and who's budget the positive effect actually can be seen in. This was the reason for also contacting and interviewing responsible for Häslostaden, what kind of effects this have on the demand side of medical care. As mentioned, the result was that they did not use HTA for decisions. To facilitate the use of HTA, a change in mind set and willingness to measure methods instead of price per unit needs to be established within the county council leadership that defines the goals and budgets for the hospitals.

¹ There were to 5,241,139 people living in these areas and 9,851,017 in the whole of Sweden in the December, 2015 (SCB, n.d). This gives a ratio of $5,241,139/9,851,017 = 53.2\%$.

² The assumption of 165 tenders in 2015 gives a ratio of $7/165 = 4,2\%$.

6.2 Today's incentive structure

This brings on the problem with the incentives. Somehow, there must be a clear incentive for the purchaser to use HTA, not just because of the social benefits but also for a specific hospital or a budget. For an implementation to be lasting and successful, the cost carrying clinics and hospitals need to recognise why and how to use HTA. In other words, there must be a demand for changes in methods. Mrs. Siegenthaler's points out that these kind of initiatives might be better received if it comes from the executive committee group who is reasonable. This is connected with acceptance that is discussed in section 6.4 in this paper.

6.3 Knowledge level

There seems to be a need for further education in this field regarding the use and definition of HTA. Another result from the interviews were that the knowledge about HTA and health economic evaluation was on a variety of different levels. It seems also as if HTA and health economy sometimes were mixed up. This can be due to that there are different definitions of HTA and that health economy is a more common used term, hence, more well known. It raises the question, how could a HTA process be successfully achieved if the preconditions and terms are not understood in the same way between participants? A finding is that price per unit of a product, as it often is evaluated in today's tender processes, is not of the main importance and the best way to seek for methodology improvements with HTA.

6.4 Acceptance from the healthcare profession, and timing

One aspect that presented itself and that needs to be considered, is the timing. During a tender process, the county councils normally gather the most prominent experts in the field of methods for the intended tender, as reference group. To suggest to make a HTA analysis during the tender process might therefore be offending for the health care professionals within those expert groups.

6.5 How should HTA reports be used for MDD products in Sweden?

This section will discuss advantages and possible disadvantages or even risks when using HTA for MDD products.

What if HTA would be used for every in all tenders? For the fact that resources are limited, it does not make sense to use HTA for every method where a MDD classified product are being used. One must consider the choice of subject for HTA carefully to give the highest societal utility. It is of great importance to define the question that the HTA should cover.

Another aspect is the time and resources that it takes to conduct a HTA. Since a HTA should be transparent, involve health care professionals and other experts, a breakeven calculation might be of use before the decision to conduct a HTA.

Additional fear is that it might delay the launch of new innovative methods. A delay would possible mean lost health economic gains. Especially, since a lot of MDD products have a short life time cycle, for examples IT related products. The time for conducting a HTA report relative the product life cycle must be considered.

One characteristic for the medical technology industry is that it is heterogenic. There are lots of products without patent protection and products that are being sold in low volume to low monetary value. This might mean that not all products finance the resources and to conduct HTA analysis. Therefore, we might lose new innovative products coming to the Swedish market.

One important aspect that would make the HTA process more accessible would be if there were one commonly accepted definition of HTA acknowledged by TLV, SBU, health care professionals, the academy, the purchasing organisations and the industry.

7. Conclusion

To clarify, HTA cover a method in which a MDD product can be a key component. A MDD product can also initiate the need to conduct a HTA if or when introducing the product changes the method used. This report has not found any specific pattern on the use of HTA with the restrictions in this paper.

This paper shows that HTA is used today, but only in limited extent in Sweden's three biggest healthcare providers, Stockholm County Council, Region Gotland, Region Skåne and Region Västra Götaland. The estimated use of HTA is 4.2 %.

For the sub-question why HTA is not being used, this report can conclude that it is because of budget structures, the incentive structures, relatively low knowledge about HTA and acceptance from involved parties. The number of HTA analysis made within the evaluated county councils are too few to make a reliable conclusion about why HTA has not been used in 95.8% of the tenders.

8. Suggestions for further research

- When and why is HTA suitable and can we defined for which MDD products?
- What is the driving force for the respective parties, academia, healthcare and industry to conduct a HTA?
- If the industry invests and conducts HTA reports for MDD products, how well will they be accepted and influence the decision in tenders?
- With the assumption that a HTA process delays the time to market for new innovative products, are there any other decision making tools that are more suitable relative HTA?
- Can a HTA report be conducted at one county council and be valid for other county councils without adaptation to local demands or characteristics?
- How does the procurement law affect HTA and vice versa?
- Does the regional purchasing level effect the use of HTA in a negative way compare to a national system, like TLV?

9. References

- Britton, M. & Jonsson, E., 2002. Impact of health technology assessments. Some experiences of SBU. *Int J Technol Assess Health Care*. 2002, Volume 18, pp. 1070-1080.
- Carlsson, P., 2004. Health technology assessment and priority setting for health policy in Sweden. *International Journal of Health Technology Assessment*, 20(1), pp. 44-54.
- Consumer Affaris, 2010. *Interpretative document of the commission's services, placing on the market of medical devices*, Brussels: European Commission.
- Draborg, E., Gyrd-Hansen, D., Poulsen, P. B. & Horder, M., 2005. International comparison of the definition and the practical application of health technology assessment. *International Journal of Technology Assessment in Health Care*, pp. 89-95.
- Drummond, M. F. et al., 2008. Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Technology Assessment in Health Care*, pp. 244-258.
- Drummond, M. et al., 2015. *Methods for the Economic Evaluation of Health Care Program*. 4th ed. Oxford: Oxford Univeristy Press.
- EUnetHTA, n.d.a. *History*. [Online]
Available at: <https://eunethta.fedimbo.belgium.be/about-us/history>
[Accessed 17 May 2016].
- EUnetHTA, n.d.b. *Common questions*. [Online]
Available at: <http://www.eunethta.eu/about-us/faq#t287n73>
[Accessed 17 May 2016].
- Felix, U. A., 2016. *Organisation*. [Online]
Available at: <http://www.vardgivarguiden.se/utbildningutveckling/vardutveckling/hta/organisation/>
[Accessed 26 April 2016].
- García-Altés , A., Ondategui-Parra, S. & Neumann , P. J., 2004. Cross-national comparison of technology assessment processes. *International Journal of Health Technology Assessment in Health Care*, 20(3), pp. 300-310.
- INAHTA, 2016. *Welcome to INAHTA*. [Online]
Available at: <http://www.inahta.org/>
[Accessed 16 May 2016].
- International Society for Pharmacoeconomics and Outcomes Research, 2013. *Pharmacoeconomic Guidelines Around The World*. [Online]
Available at: <http://www.ispor.org/PEguidelines/countrydet.asp?c=21&t=1>
[Accessed 17 May 2016].
- Jonsson, E., 2009. History of health technology assessment in Sweden. *International Journal of Technology Assessment in Health Care*, Volume 25, pp. 42-52.
- Jonsson, E. & Banta, D. H., 1994. Health care technology in Sweden. *Health Policy*, Volume 30, pp. 257-294.

Läkemedelsverket, 2015. *Vår vision: En ledande kraft i samverkan för bättre hälsa*. [Online]
Available at: <https://lakemedelsverket.se/overgripande/Om-Lakemedelsverket/>
[Accessed 8 May 2016].

Medical Products Agency, 2006. *An Introduction to Rules and Regulations*. [Online]
Available at: <https://lakemedelsverket.se/english/product/Medical-devices/An-Introduction-to-Rules-and-Regulations/>
[Accessed 6 May 2016].

Medical Products Agency, 2014. *About the Medical Products Agency*. [Online]
Available at: <https://lakemedelsverket.se/english/overview/About-MPA/>
[Accessed 23 May 2016].

Mehmood Birchall Shah, S., Barron, A., Klinger, C. & Wright, J. S., 2014. A regulatory governance perspective on Health Technology Assessment (HTA) in Sweden. *Health Policy*, pp. 27-36.

NICE, 2013. *Guide to the methods of technology appraisal 2013*. [Online]
Available at: <https://www.nice.org.uk/article/pmg9/chapter/foreword>
[Accessed 23 May 2016].

Region Skåne, 2016. *Så går en upphandling till*. [Online]
Available at: <http://www.skane.se/organisation-politik/Att-gora-affarer/upphandling/sa-gar-upphandling-till/>
[Accessed 17 May 2016].

SBU, 2014. *Utvärdering av metoder i hälso- och sjukvården: En handbok*. 2 ed. Stockholm: Statens beredning för medicinsk utvärdering (SBU).

SBU, n.d.a. *Regionala HTA-organisationer*. [Online]
Available at: <http://www.sbu.se/sv/om-sbu/svenska-hta-organisationer/>
[Accessed 18 May 2016].

SBU, n.d.b. *Vårt uppdrag*. [Online]
Available at: <http://www.sbu.se/sv/om-sbu/vart-uppdrag/>
[Accessed 15 May 2016].

SCB, n.d. *Befolkningsstatistik*. [Online]
Available at: http://www.scb.se/sv/Hitta-statistik/Statistik-efter-amne/Befolkning/Befolkningens-sammansattning/Befolkningsstatistik/#c_li_26051
[Accessed 25 April 2016].

Skånes universitetssjukhus, 2015. *HTA och ordnat införande*. [Online]
Available at: <https://www.skane.se/sv/Webbplatser/Skanes-universitetssjukhus/Organisation-A-O/HTA---Kunskapsbaserad-var/d/>
[Accessed 25 May 2016].

Skånes universitetssjukhus, 2015. *Rapporter och utlåtanden*. [Online]
Available at: http://www.skane.se/sv/Webbplatser/Skanes-universitetssjukhus/Organisation-A-O/HTA---Kunskapsbaserad-var/Avslutade_projekt/
[Accessed 3 May 2016].

Socialstyrelsen, n.d. *Om socialstyrelsen*. [Online]
Available at: <http://www.socialstyrelsen.se/omsocialstyrelsen>
[Accessed 3 May 2016].

Sorenson, C., Drummond, M. & Kanavos, P., 2008. *Ensuring value for money in health care: The role of health technology assessment in the European Union*. Copenhagen: WHO Regional Office for European Union.

Swedish Competition Authority, n.d. *About the public procurement rules*. [Online]
Available at: <http://www.konkurrensverket.se/en/publicprocurement/about-the-public-procurement-rules/>
[Accessed 5 May 2016].

Sveriges Kommuner och Landsting, 2015. *Kommuner och Landsting*. [Online]
Available at: <http://skl.se/tjanster/kommunerlandsting.431.html>
[Accessed 4 May 2016].

Sveriges Kommuner och Landsting, n.d. *The role of the county councils and the region's*. [Online]
Available at:
<http://skl.se/tjanster/englishpages/municipalitiescountycouncilsandregions/theroleofthecountycouncilsandtheregions.1303.html>
[Accessed 24 May 2016].

The Dental and Pharmaceutical Benefits Agency, 2014. *Our mission*. [Online]
Available at: <http://www.tlv.se/lakemedel/Vart-lakemedelsuppdrag/>
[Accessed 17 May 2016].

The Dental and Pharmaceutical Benefits Agency, 2016. *Economic evaluations of medical devices*. [Online]
Available at: <http://www.tlv.se/Medicinteknik/Vart-medicinteknikuppdrag/>
[Accessed 23 May 2016].

The National Agency for Public Procurement, n.d. *About us*. [Online]
Available at: <http://www.upphandlingsmyndigheten.se/en/omossmeny/about-us/>
[Accessed 5 May 2016].

The National Agency for Public Procurement, n.d. *About the public procurement rules*. [Online]
Available at: <http://www.upphandlingsmyndigheten.se/en/publicprocurement/about-the-public-procurement-rules/>
[Accessed 6 May 2016].

Thorin, I., 2014. *In English*. [Online]
Available at: <https://www2.sahlgrenska.se/sv/SU/Forskning/HTA-centrum/In-English/>
[Accessed 20 May 2016].

Thorin, I., 2016. *HTA-centrums publicerade rapporter*. [Online]
Available at: <https://www2.sahlgrenska.se/sv/SU/Forskning/HTA-centrum/Hogerkolumn-undersidor/Publicerade-rapporter/>
[Accessed 12 May 2016].

Vårdgivarguiden, n.d. *HTA-rapporter*. [Online]
Available at: <http://www.vardgivarguiden.se/utbildningutveckling/vardutveckling/hta/hta->

rapporter/

[Accessed 20 May 2015].

Zethraeus, N., 2009. *Health Technology Assessment (HTA) och ekonomisk utvärdering av hälso- och sjukvårdens metoder*, Stockholm: Karolinska Institutets folkhälsoakademi.

10. Appendix

The e-mail in Swedish:

Hej!

Mitt namn är Emma Lund och jag skriver min c-uppsats på Lunds Universitet inom hälsoekonomi.

Målet är att göra en liten kartläggning av hur Health Technology Assessment (HTA) används för inköp av medicinteknik inom slutenvården.

Avgränsning för uppsatsen: Medicintekniska produkter för slutenvård

Målet med uppsatsen: Kartlägg hur HTA används vid inköp av medicintekniska produkter inom slutenvården.

Jag skulle uppskatta väldigt mycket om du kan hjälpa mig och svara på lite frågor:

1. Har du använt dig av HTA vid inköp?
2. Har ni en lista på produkterna som ni använt HTA till?
3. Har den lokala HTA-organisationen eller SBUs rapporter legat till grund för upphandlingarna?
4. Om du ej har använt dig av HTA, varför inte?
5. Vad skulle krävas för att ni ska använda er av HTA?

Ytterst tacksam för svar

Med vänlig hälsning

Emma Lund