Technology assessment of innovative operating room technology

Master Thesis

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University of Twente
MSc Health Science/Health Care Management
School of Management and Governance

Under the authority of:
The Netherlands Cancer Institute

January 2009

NKI-AVL

University of Twente
Enschede - The Netherlands

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Executive summary

Problem definition
Technologies in health care are evolving rapidly. The dynamic nature and the tempo of the development of new technologies that is foreseen in the coming years are challenging the surgeons and other decision makers. Hospitals are often stimulated to make decisions before there is definitive evidence on their efficacy and impact (Greenberg and Pliskin, 2008). Hospitals face challenges which stimulate them to distinguish themselves from others. The government wants to enhance the market forces in the health care system, the industry is offering new technology and the insurance companies do not want to counterbalance for interventions which have not shown added value. Health Technology Assessment (HTA) is often used to answer the question whether the new technology should be implemented into clinical practice. HTA uses traditional clinical and economical research strategies which can be time-consuming and expensive. Nowadays technologies are modified after dissemination, which requires a dynamic way of assessment. The complexity of the technologies and HTA has increased so much that traditional HTA needs to be adapted and specified for groups of technologies, in this case surgical innovations.

Research question
What type of Health Technology Assessment (HTA) should be used or how should HTA be adapted to make it applicable for surgical innovations in an early stage of diffusion?

Methodology
Based on the literature a HTA framework with a process model and a list of variables is designed. The DaVinci Surgical System (DVSS) is used as a case study to evaluate the completeness of the list of variables and review the assessment methods currently used to assess surgical innovations. Semi structured interviews with 5 surgeons and a systematic review have been performed.

Conclusion
HTA for surgical innovations is characterized by a broad spectrum of variables. The evaluation of the theoretical framework revealed that the eventually list of attributes seems complete. Based on the results of the interviews and the available research methods for early assessment, the following aspects of surgical innovations should be assessed in an early stage of diffusion: 'environmental preconditions', 'accuracy, reliability & validity', 'reinvention', 'applicability', 'effectiveness', 'social outcomes', 'safety', 'risk of malpractice litigation', 'acceptability of the user' and the 'ethical considerations'. These aspects seem to be relevant and possible to assess in that stage. When starting HTA, all aspects should be taken into consideration for the assessment, but in the actual design, only those are included that are estimated relevant for the particular technology, environmental interaction and phase of diffusion.

Only traditional research designs are currently used to evaluate surgical innovations, which can be expensive and time-consuming. Technologies may be assessed at different stages of diffusion and maturity, which requires a dynamic, iterative and ongoing assessment with use of diagnostic and intervention strategies. CTA combined with HTA (CHTA) using diagnostic and intervention strategies seem a possible solution. Decision analysis and value-of-information (VOI) analysis should be used to determine whether an innovation should be adopted, whether additional evidence to further inform that

decision is worth gathering, and what kind of information is of the greatest value (e.g. which aspects need to be assessed). These techniques cannot only help to determine whether additional research is worthwhile, but can also help to determine how research efforts should be prioritized. Prospective research should be performed to evaluate this.

Recommendations
The list of variables and the prioritization of the aspects can probably be validated with use of VOI analyses and/or a study with a larger population including also other actors then surgeons alone (e.g. management or insurance companies).

A study determining/explaining the factors influencing the diffusion of a surgical innovation could give rise to new strategies enhancing a smooth diffusion.

Discussion
When assessing surgical innovations, more emphasis should be on economical and ethical aspects. Politicians, patients and physicians all want the (perceived) best treatment, best care and best cure. The newest technology is often perceived as the best treatment, which is generally most expensive and may not be necessary. Here there are two perspectives: individual patient perspective and public (economical) perspective. This is however a difficult and ethical discussion since most people want the best (perceived) treatment for themselves and their loved ones.

Preface

This master thesis is initiated by the Netherlands Cancer Institute (NKI) and the Antoni van Leeuwenhoek Hospital (AVL), both located in Amsterdam. The NKI and AVL conduct research together. The NKI is a research institute. The acquired insights of the NKI are applied in the clinical setting of the AVL.

The NKI is an internationally recognized centre of scientific excellence in many key areas related to cancer. Identifying the best method of diagnosing and treating patients is the pursuit of the collaboration NKI-AVL.
Scientific research groups in the NKI are organized in divisions. The research interests of the Division of Surgical Oncology (DOSO) reflect clinical reality and extend far beyond surgery itself into areas such as diagnostic and therapies for inoperable tumours.
In DOSO a project is being designed -at the time of writing- in which a number of innovative operating theatres will be constructed in cooperation with the University of Twente (UT), and one or more major industrial partners. Minimal Invasive Surgery (MIS) will be the topic of this project. It is foreseen that new (combinations of) molecular imaging, robot technology, per operative imaging and navigation- and tumour destruction technologies will be developed and introduced. The introduction process itself and the impact of such innovations will be studied.
The investments in such innovations will be huge and therefore the NKI-AVL/DOSO wants to organize the decision making process and introduction of such (promising) innovations in a conscientious manner. Especially the innovations in an early developmental / adoptive stage are important, because there is little known of the efficacy and impact. The NKI-AVL wants to develop their (individual) set of criteria for strategic technology planning and assessment with respect to their particular environment.

This study is performed for the education program (master thesis) of the MSc Health Sciences, Department of Management and Governance, University of Twente, the Netherlands. Supervision of this study has been performed by two persons (see Table 1.1).

NAME	***INSTITUTE***	***FUNCTION***	***ROLE IN SUPERVISION***
• Prof. Dr. W.H. van Harten	• Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital (NKI-AVL) and University of Twente	• Member of the Executive Board of Directors of the NKI-AVL • Professor on the chair Quality Management of Health Care Technology	• First supervisor from university and supervisor internship
• Dr. J.M. Hummel	• University of Twente	• Assistant professor 'Management of Medical Technology'	• Second supervisor from university

Table 1.1: Supervisors

Acknowledgements

I gratitude my supervisors Prof. Dr. W.H. van Harten and Dr. J.M. Hummel for the guidance they gave me through the process of development of the theoretical framework. They helped me to organise my thoughts and intensions. Furthermore I thank the surgeons that were willing to share their experience and opinions regarding the introduction and assessment of the DaVinci Surgical System.

Besides performing the master thesis I have been working as an occupational therapist in the University Medical Centre Groningen, location Beatrixoord in Haren. I would like to thank my colleagues for the support and the interest they showed, especially Frans Valster. Because of the distance between Enschede and Haren I stayed half the time with my parents. I gratitude my parents, because it has not always been easy to have me back home, but I was always welcome. Then, last but not least, special thanks for my partner in love, Gert, who observed my frustrations and inspired me to go on.

Enschede, 14th January 2009

Ingrid Nota

Table of Contents

1. Introduction

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Adopting surgical innovations

Surgical innovations are often introduced in an attempt to improve treatment or enhance institutional productivity. Technologies in health care are evolving rapidly. For example, in recent years almost all operation teams have adopted endoscopic surgery and Minimal Invasive Surgery (MIS) and a few hospitals have started to use surgical robots.

Developing, adopting and combining new technologies is a continuous process. The dynamic nature and the tempo of the development of new technologies that is foreseen in the coming years are challenging the surgeons and other decision makers. Hospitals are often stimulated to make decisions before there is definitive evidence on their efficacy and impact (Greenberg and Pliskin, 2008). Hospitals face challenges which stimulates them to distinguish themselves from others. The government wants to enhance the market forces in the health care system, the industry is offering new technology and the insurance companies do not want to counterbalance for interventions which have not shown added value.

Introducing new technologies can have a great impact. It can have consequences for the safety of the patient, logistic consequences, the functioning of operating room teams, job performance/satisfaction, cost-effectiveness, etc. The decision to adopt a new technology should depend on evidence. Evidence can be difficult, time-consuming and expensive to collect (Claxton, Cohen & Neumann, 2005). Hospitals make great investments to distinguish themselves. When the innovations are introduced into the hospital, the impact of the technology should be studied. The results can convince the insurance companies of the added value.

New technologies are even adopted despite poor evidence (Meakins, 2002; Danjoux et al., 2007). The development and introduction of surgical innovations has often depended upon a surgeon performing a case series, not on high quality research (Meakins, 2002), even though Evidence Based Medicine (EBM) is an important aspect in the health care system nowadays. Evidence Based Medical Technology (EBMT) deserves the same recognition.

Health Technology Assessment

Since the 1970's Health Technology Assessment (HTA) is often used to answer the question whether the new technology should be implemented into clinical practice (Leys, 2003; Berg, Van der Grinten, & Klazinga, 2004). The complexity of the HTA has increased so much that input from other research fields is necessary to maintain its relevance (Battista, 2006). Douma, Karsenberg, Hummel, Bueno-de-Mesquita & Van Harten (2007) concluded that Constructive Technology Assessment (CTA) can be used as a complementary approach. CTA takes into account the dynamics of the technology by emphasizing sociodynamic processes (Douma et al., 2007; Retèl, Hummel, & Van Harten, 2008).

Possibly, HTA combined with CTA provide basic aspects to develop a framework for introducing and assess surgical innovations in an early stage of diffusion.

This master thesis tries to develop a theoretical framework regarding HTA for surgical innovations. First the research objectives and questions are mentioned, and then a definition of surgical innovation is developed. Chapter 4 discusses several theories related to the introduction of innovations in health care and Health Technology Assessment. A theoretical framework for HTA for surgical innovations is developed. This theoretical framework is evaluated using the DaVinci Surgical System as a case study.

2. Research Objectives and Questions

2.1 Objectives

The objective of this master thesis is to develop a theoretical framework considering the decision-making process for adopting and introducing surgical innovations. This will be applied to an existing but recently introduced technology to verify the validity of the model in a retrospective way. In this case robot surgery will be used. The objective is divided into the general objective and specific objectives.

- **General objective**
  The development of a theoretical framework for Health Technology Assessment (HTA) for surgical innovations *in an early developmental / adoptive phase.*

- **Specific objectives**
  A. *The theoretical framework should contain a set of potentially relevant aspects on micro, meso and macro level.*
  B. *Attention should be paid to the phases of development and diffusion.*
  C. *Also attention should be paid to the assessment/research methods most appropriate for innovations in an early phase of diffusion.*
  D. *Application of the theoretical framework to robot surgery.*

2.2 Research Questions

The research question is split into a general question and some specific questions to narrow the focus of the proposed research. The distinction between them is in terms of specificity. The general research question is abstract. The specific research questions are more specific, detailed and concrete.

- **General research question**
  'What type of Health Technology Assessment (HTA) should be used or how should HTA be adapted to make it applicable for surgical innovations in an early stage of diffusion?'

- **Specific research questions**
  A. *What paradigm (e.g. Constructive Technology Assessment) can be used to make HTA more applicable for surgical innovations in an early stage of diffusion?*
  B. *Which aspects of the adoption / diffusion / implementation of a surgical innovation in an early stage of diffusion are important to assess?*
  C. *How are these aspects measurable?*
  D. *Which aspects are measured during the diffusion of Robot Surgery, how are these aspects measured and what are the results of these studies?*
  E. *Which aspects need to be assessed in future studies during the diffusion of Robot Surgery to enhance complete diffusion and which method can be used?*

2.3 Significance

The theoretical framework can have an important role in the decision-making process for adopting surgical innovations in an early developmental / adoptive phase. It could have an important role in deciding which important aspects to assess and how they need to be assessed. Eventually it could support the evidence based medicine culture, make sure the most effective treatment is chosen for the individual patient in the most efficient manner.

3. Surgical Innovations

The definition of surgical innovation

Although a frequently used term, surgical innovation is not clearly defined. Linguistic meaning is highly context-dependent, so it is possible that the definition in this master thesis does not fit every situation. Though for the purposes of this master thesis an attempt is made to define the main subject of this master thesis. Several definitions of 'innovation' are used to define “surgical innovations”.

Greenhalgh, Robert, Bate, Macfarlane and Kyriakidou (2005) reviewed the literature and found a lot of definitions of 'innovation'. The much-quoted definition of innovation of Rogers (2003) is:

'An innovation is an idea, practice or object that is perceived new by an individual or other unit of adoption. It matters little, so far as human behaviour is concerned, whether or not an idea is objectively new as measured by the lapse of time since its first use or discovery.'

Goes and Park (1997) offer the following definition:

'A health care innovation is a medical technology, structure, administrative system, or service that is relatively new to the overall industry and newly adopted by hospitals in a particular market area.'

Greenhalgh et al. (2005) constructed a new definition for the purposes of their study.

'An innovation in health service delivery and organisation is a set of behaviours, routines and ways of working, along with any associated administrative technologies and systems, which are:

- *perceived as new by a proportion of key stakeholders;*
- *linked to the provision or support of health care;*
- *discontinuous with previous practice;*
- *directed at improving health outcomes, administrative efficiency, cost-effectiveness, or use-experience; and*
- *implemented by means of planned and coordinated action by individuals, teams, or organisations'.*

All definitions have aspects that are accurate for the definition of surgical innovations, but non are specific enough. They need to be adapted. The definition of Rogers (2003) describes a very broad definition of innovation as an idea, practice or object. It also provides a broad view of the adopter as an individual or other unit of adoption. Though, this definition states that it matters little whether or not an innovation is new. In this master thesis newness is important, because the central point of this master thesis is assessment in an early phase of diffusion. Newness is measured by the lapse of time since its first use. Applying existing ideas, practices or technologies in a new field or setting are also qualified as an innovation. The definition of Goes and Park (1997) describes the essential criterion of newness for an innovation, but this definition mentions “overall industry”, which does not fit the terminology of this master thesis. This master thesis is about diffusion between health care organizations; “overall industry” implies also the developers of the innovation. Greenhalgh et al (2005) specifically mention administrative technologies and systems, which is not a specific subject of this master thesis.

For defining 'surgical innovations' the definitions above are adapted and combined:

'A surgical innovation is an idea, practice or object (technology) that:

- *is used in the operating room and by the operation team;*
- *is in an early phase of diffusion;*

- *is discontinuous with previous practice;*
- *that affects routines and/or ways of working of the operating team and/or the organisation (logistics);*
- *directed at improving the quality of care/cure (as stated by the IOM*[1] *(2001)) or the user experience; and*
- *is implemented by means of planned and coordinated action by individuals, teams, or organisations'.*

The definition is very general to make the theoretical framework applicable for different kinds of surgical innovations. Surgical innovations cover a broad spectrum, ranging from minor modifications in clinical care and surgical technique to complex and sometimes risky experimental surgery. Uncertainties and disagreement exists as to what is an acceptable variation on an existing technique versus when the introduction of an innovation amounts to human experimentation. In general, complex innovations have greater consequences for the team's routines and ways of working and the environment. This master thesis concerns the more complex surgical innovations. Therefore aspects regarding the team's routines and ways of working and the environment are included in the definition. This definition will be used to determine aspects/variables important to assess in surgical innovations.

1 The IOM (2001) states that care of good quality is safe, effective, patient-centered, timely, efficient and equitable.

4. Theoretical Framework

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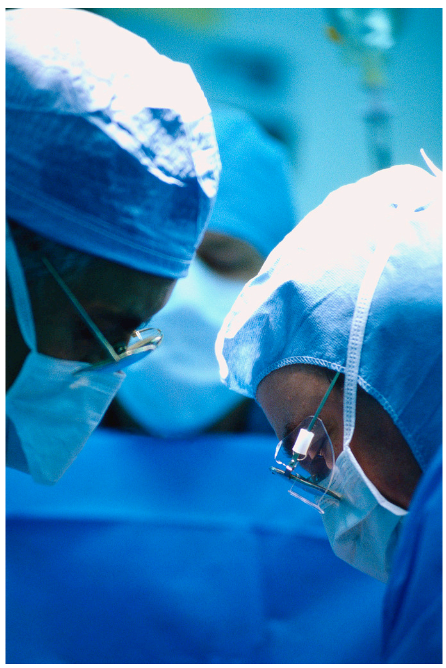


4.1 Introduction

This chapter discusses several theories related to the introduction of innovations in health care and Health Technology Assessment. The theories are first described in general and then more specific on surgical innovations. A theoretical framework for surgical innovations is developed.

The adoption and diffusion of innovations in health service organisations is a process with an important influence on HTA. This process is described first.

4.2 Adoption and diffusion of innovations

Several theories describing the process of adoption and diffusion of innovations are discussed in this chapter. These processes are important to understand because they influence the (timing of) assessment. They describe how innovations spread within and between organizations and which factors influence the diffusion process. These factors can be used to define attributes to assess.

The mechanisms by which innovations spread include adoption, assimilation, diffusion, dissemination, implementation and sustainability of innovations. These mechanisms are widely studied. To understand the differences between the mechanisms they are defined below. These words are being used interchangeably. Still it is important to know the (sometimes subtle) distinctions and decrease confusion by using the right terminology.

Adoption (in relation to the individual) is defined as the decision to use the innovation as the best course of action available (Rogers, 2003). Other definitions are likely. They imply that people and organisations choose rationally to adopt innovations because of some actual or perceived advantage. But, the adoption of advantageous innovations often fails to take place; on the contrary, adoption of disadvantageous innovations is common. Also adoption (and non-adoption) is not always a rational process, nor is adoption a single decision (Greenhalgh et al., 2005).

In the organisational context, adoption is more usually referred to as *assimilation*, which reflects the complex adjustments that are often needed in the organizational setting (Meyer & Goes, 1988). To avoid ambiguity, the term 'assimilation' will be preferred instead of 'adoption'.

Diffusion is defined as the process by which an innovation is communicated through certain channels over time among members of a social system (Rogers, 2003). Diffusion is a passive phenomenon of adoption by individuals and organizations (Greenhalgh et al., 2005), whereas *dissemination* is actively spreading a message to defined target groups (Mowatt, Thomson, Grimshaw & Grant, 1998). Mowatt et al. (1998) defines *implementation* as dissemination plus action to actively encourage the adoption recommendations contained in the message.

Sustainability is when new ways of working and improved outcomes become the norm. Not only have the process and outcomes changed, but the thinking and attitudes behind them are fundamentally altered and the systems surrounding them are transformed in support (NHS Modernisation Agency, 2003). This implies that further innovativeness or reinvention is not possible. Therefore this term is rarely used (Greenhalgh et al., 2005).

A wide range of conceptual and theoretical models for the adoption, assimilation, diffusion, dissemination, implementation and sustainability of innovations, exists (Greenhalgh et al., 2005). This master thesis centralizes surgical innovations in an early stage of diffusion. Therefore the models for sustainability are excluded.

The process of adopting new innovations has been studied for over 30 years, and one of the most popular adoption models is described by Rogers in the five editions of his book 'Diffusion of innovations' (1962, 1971, 1983, 1995, 2003). Classical diffusion of innovations research, as set out by Rogers (1962), is a theory that demonstrated a consistent pattern of adoption of new ideas over time by people in a social system (Greenhalgh et al., 2005). The cumulative adoption of innovations by a population follows an S-shaped pattern. First there is a slow initial (lag) phase, followed by an acceleration (take-off) in the number of people adopting in each time period, and then a corresponding deceleration, and finally a tail as the last few individuals who are going to adopt finally do so (Greenhalgh et al., 2005) (see the cumulative frequency distribution in Illustration 4.1). Based on this distribution Rogers (1962) defined five adopter categories: (1) innovators, (2) early adopters, (3) early majority, (4) late majority, and (5) laggards.

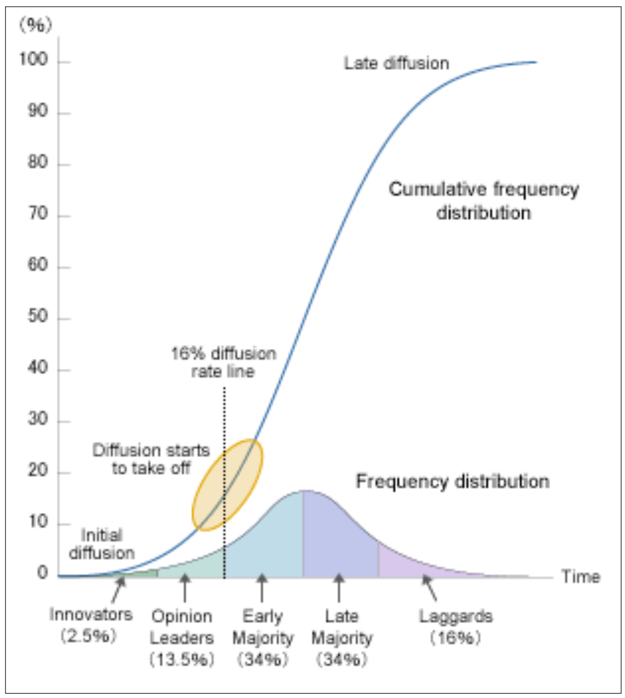


Illustration 4.1: The 16% diffusion rate theory (Tanahashi, 2008)

These categories follow a bell-shaped curve; very little innovators adopt the innovation in the beginning (2,5%), early adopters (also called opinion leaders) making up for 13,5% a short time later, the early majority 34%, the late majority 34% and after some time finally the laggards make up for 16% (see Illustration 4.1). These categories are not fixed personality traits of individuals but are mathematically defined cut-offs for the adopters of any particular innovation by a particular population (Rogers, 2003).
The distribution of the adoption is being influenced by several factors. Table 4.1 describes the attributes of innovations that are associated with their successful adoption, which is based on an extensive review of empirical studies in the sociological literature (Rogers, 1995).

1.	***Relative Advantage*** - measured, for example, in economic terms, social prestige, convenience or satisfaction.	
2.	***Compatibility*** - with existing practices and values, past experiences, and needs of potential adopters and their social system.	
3.	***Complexity*** - the degree to which the innovation is perceived as difficult to understand and use.	
4.	***Trialability*** - the degree to which an innovation may be experimented with on a limited basis.	
5.	***Observability*** - the degree to which the results of an innovation are visible to others.	
6.	***Reinvention*** - the extent to which the innovation is changed or modified by the user in the process of adoption and implementation.	

Table 4.1: Attributes of innovations that have been shown in empirical studies to influence their rate and extent of adoption by individuals (based on an extensive review of the sociological literature by Rogers (1995).

Also opinion leaders have an important role in the diffusion process. Rogers compared the bell-shaped curve to the S-shaped cumulative frequency distribution of product diffusion. The 16% line marks the cut-off point between innovators and early adopters/opinion leaders and later adopters, and roughly coincides with the point where the S-curve starts to increase dramatically (see Illustration 4.1). Based on that fact Rogers discovered that the key to product diffusion is diffusion amongst opinion leaders (see Illustration 4.1). Thus, Rogers put forward the 16% diffusion rate theory (Rogers, 2003).

According to Rogers' innovator theory, in general, diffusion amongst opinion leaders holds the key to product diffusion as a whole. Although it is innovators who purchase products at the earliest stages soon after their release, they tend to focus on products' novelty value rather than their essential benefits that might appeal to the majority of consumers. On the other hand, opinion leaders, tend to focus not on mere novelty value – like the innovators - , but on newly available benefits that differ from products in the past (Rogers, 2003). The sooner a product is adopted, the more its actual uses differ from the uses and usage scenarios that the developers originally had in mind. Consequently, you could say that it is the role of opinion leaders to actually come up with uses for products. Effectively, it is not until opinion leaders come up with actual ways of using a product that it starts to find its place in the market (Tanahashi, 2008).
In addition to this, opinion leaders are generally thought to have a great deal of influence over other consumers. When word-of-mouth networks are formed based around opinion leaders, it really paves the way for product diffusion. That is why opinion leaders are said to hold the key to product diffusion (Tanahashi, 2008).

Geoffrey Moore has questioned the commonly accepted innovation diffusion theory which states that opinion leaders hold the key to product diffusion. Moore (1991) demonstrates that there is a so-called 'chasm' that cannot easily be bridged between the initial market, consisting of innovators, early adopters (opinion leaders) and mainstream market, consisting of the early and late majorities. The innovators and early adopters of high-technology innovations are fundamentally different from later adopters. Persuading the later adopters requires a shift from product-centred values to market-centric values. Innovators and early adopters want to be unique, whilst later adopters desire for conformity, reliability, warranty and service. The later adopters do not like uncertainty. Complex and risky

innovations that require skills and expertise are not easily adopted (Meyer & Goes, 1988).
This theory is in line with the competitive and innovative behaviour of some health care organisations. Nowadays the governments stimulate the health care system to be more depending on the market forces, which means health service organisations have to distinguish themselves and be more competitive. Some health care organisations will distinguish themselves by being the most innovative. Von Hippel (1988) suggested that 'innovative behaviour is a strategic activity by which organisations gain and lose competitive advantage'.

Therefore, rather than thinking exclusively in terms of diffusion amongst early adopters (opinion leaders), it is vital for the diffusion to take appropriate steps to target the early majority (creating examples) from the very beginning in order to bridge the chasm and gain access to the mainstream market on the other side. Probably the theories of both Rogers and Moore can be used parallel: If the opinion leaders hold the key to product diffusion, they can bridge the 'chasm of uncertainty' by studying the impact of the innovation. The early adopter phase is the phase where the most research needs to be performed.

The theory of Rogers is sufficient to describe the adoption of individuals and the role of opinion leaders. But it takes little or no account of the complex process of adoption/assimilation of innovations at the organisational level (Greenhalgh et al., 2005). Rogers (2003) does not refer to a complex organization as the adopter of the innovation, or to organizational features as independent variables affecting the process (Greenhalgh et al., 2005). Rogers (2003) acknowledges these criticisms by including a chapter on innovation in organizations and highlighting that 'teachers are school employees and that most doctors work in hospitals or in a group practice". Probably the diffusion between hospitals will follow the same curve and hospitals can be categorized the same way as individuals, because physicians and surgeons themselves can and do play an important role in the choice of technologies they use.

Category	Characteristics
Characteristics of leader	Leader has a positive attitude towards change.
Structural features of the organisation	Large size
	Presence of complex knowledge and expertise
	Decentralized power and control
	Informal rules and procedures
	Well developed interpersonal networks
	Slack resources and cosmopolitanism
System openness	Exchange of information across inter-organizational boundaries

Table 4.2: Organizational innovativeness

Several key traditions in diffusion research focused on organisations rather than on individuals (Baldridge & Burnham, 1975; Kimberly, 1981) and studied for example organisational innovativeness. The organisational innovativeness is associated with characteristics of its leader as well as with structural features of the organisation and the exchange of information across inter-organisational boundaries (Greenhalgh et al., 2005). In Table 4.2 the characteristics of innovativeness of organisations are described in more detail. Based on these characteristics, the NKI-AVL can be categorized as an innovator.

Another problem with the theory of Rogers is that the S-shaped pattern of the cumulative adoption curve only occurs if the population is fixed and the influence of the innovation stays constant over time. If there is rapid population turnover, infusion of new people, loss of former members or a change in the market value of the innovation, the curve will cease to be S-shaped. The S-shaped adoption curve is descriptive, not exploratory or predictive. It represents an ideal diffusion process. The goal of HTA is to enhance a smooth diffusion or reject the innovation when the results are too bad.

4.3 *Paradigm's of Health Technology Assessment*

Kanter (1989) ones said: *"It is not possible to manage innovation but it is possible to design and control the contextual and organisational conditions that enhance the possibility of innovation occurring and spreading."* To design and control these conditions you need to study them. Health Technology Assessment can be used for this.
This chapter is about Health Technology Assessment (HTA) and related methodologies:

- Health Technology Assessment
- Early Health Technology Assessment
- Constructive Technology Assessment

4.3.1 **Health Technology Assessment**

HTA is a research-based, usage-orientated assessment of relevant available knowledge about problems in connection with the use of technology in relation to health and diseases. Health technology assessment (HTA) is the systematic evaluation of properties, effects, or impacts of health care technology. HTA is relevant in connection with complex problems prior to the establishment of a policy. This may be for example the establishment of a policy for treatment, the decision to adopt or reject a technology, or the health-political decisions on treatment and screening offers with consequences for the whole country. Formally, a Health Technology Assessment (HTA) is defined as 'the comprehensive, multidisciplinary and systematic assessment of the (social) consequences of using health technologies with a broad focus upon societal, economic, ethical, and legal implications using four elements: clinical, economic, patient related and organisational' (Fuchs & Garber, 1990 as cited in Poulsen, 1999; Jørgensen & Danneskiold, 1986 as cited in Poulsen, 1999). In less words: *"HTA is the systematic evaluation of properties, effects, and/or impacts of health care technology"* (Goodman & Ahn, 1999).
This definition of HTA is very broad, because it is complex to study the impact of a technology with all the various areas and methods. HTA does not make complexity disappear but offers a structure for the multifaceted basis for decisions. It is important to emphasise that the decision situation itself is beyond HTA. Besides input from HTA, many other components may form part of decision-making, for instance regarding other patients or other circumstances in the health care system and in society (Kristensen & Sigmund, 2007).
HTA can also be performed partially. Most assessments stop with a partial effort, and the Institute of Medicine (IOM) declined that these are included when we speak of HTA (IOM, 1985 as cited by Poulsen, 1999) The focus of HTA includes for instance testing or evaluating safety and efficacy, effectiveness, Quality of Life (QOL), patient preferences and costs versus benefits. These aspects can thus be assessed individually, but to know the full impact of a technology, you need a broad assessment.

HTA can be used in many ways to support policymaking. Examples are (Goodman & Ahn, 1999):

- Advice a regulatory agency about whether or not to permit commercial use of a technology;

- help health care insurers and providers to determine which technologies should be included in benefit plans;
- advice clinicians and patients about the proper use of a technology;
- help hospital managers to make technology acquisition and management decisions;
- advice governments about undertaking public health care programs;
- support the development and marketing decisions of health technology designers;
- set standards regarding the manufacture and use of technologies;
- advise investors and companies concerning transactions in the health care industry.

HTA is related to planning, administration and management, because of its methods (based on research) and because its aiming at decision-making. HTA may therefore be considered as bridging between two domains: a decision-making domain and a research domain (Battista & Hodge, 1995; Poulsen, 1999; Kristensen & Sigmund, 2007), see Illustration 4.2. In order to fulfil such a purpose, the problems in focus of a HTA must be based on the need of the decision-makers (and their advisers) for a documented basis for decisions about the use of health technology.

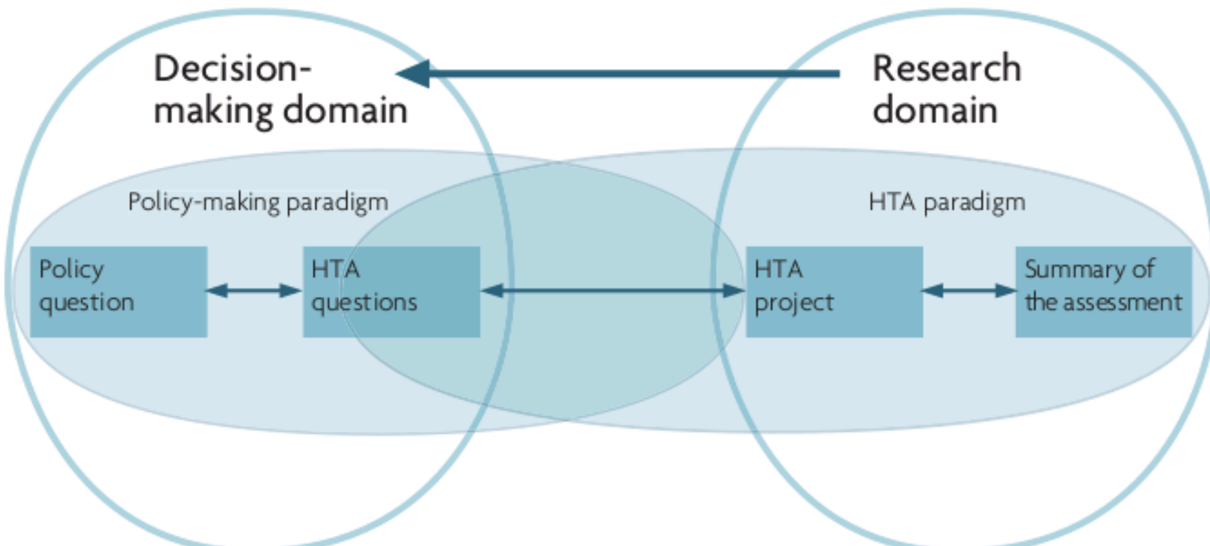


Illustration 4.2: Bridging between decision-making and research domains (Kristensen & Sigmund, 2007)

HTA is thus defined in terms of its purpose and not as a specific method (EUR-Assess Project, 1997; Kristensen & Sigmund, 2007). At a more specific level, HTA is an assessment of the preconditions for and the consequences of using health technology. These preconditions and consequences are comparable with the success factors defined by Rogers (1995) (see Table 4.1 on page 19).

HTA is a systematic, research-based approach, but there is no single method or one delimited research field. Rather, HTA is characterised by an approach which is interdisciplinary and versatile. 'Interdisciplinary' in this case means HTA is based on several scientific disciplines, namely health science, social science, natural science and the humanities. These each have their own issues, theories and research strategies, but with certain overlaps, e.g. interview and questionnaire methods. This makes that HTA considers both quantitative and qualitative research. HTA comprises analysis and assessment of various areas where the use of health technology may have consequences (Kristensen & Sigmund, 2007).

Category	Variables
Clinical parameters	1. Efficacy
	2. Safety
	3. Effectiveness
	4. Outcomes
	5. Indications
	6. Population Affected
Economic parameters	1. Efficiency – cost-minimization
	2. Costs
	3. Cost-effectiveness
	4. Cost-utility
	5. Cost-benefit
Patient-related parameters	1. Social and Environmental impact
	2. Ethics
	3. Acceptability
	4. Psychosocial Relations
	5. Other patient-related parameters
Organizational parameters	1. Diffusion - dissemination
	2. Centralization - decentralization
	3. Utilization
	4. Accessibility - equity
	5. Skills - routines
	6. Education - training
	7. Other organizational parameters

Table 4.3: Parameters of HTA (Poulsen, 1999)

Poulsen described the process of HTA, starting from identification of technologies (1), prioritizing of assessments (2), performing the assessments (3) and synthesizing (4), towards dissemination (5). Poulsen (1999) described four main groups of elements to assess: clinical parameters, economic parameters, patient-related parameters, and organizational parameters. The definitions of these main groups consist of variables, which can be found in Table 4.3.
The synthesis in the HTA process could be argued to be the most important stage in a broad, holistic,

comprehensive approach in contrast to a more partial approach. The synthesis is the critical analysis and weighing of the single elements, which makes the broad HTA information relevant for decision making; the existing information and the results of tests are collected and interpreted in order to submit judgements or recommendations (Poulsen, 1999).

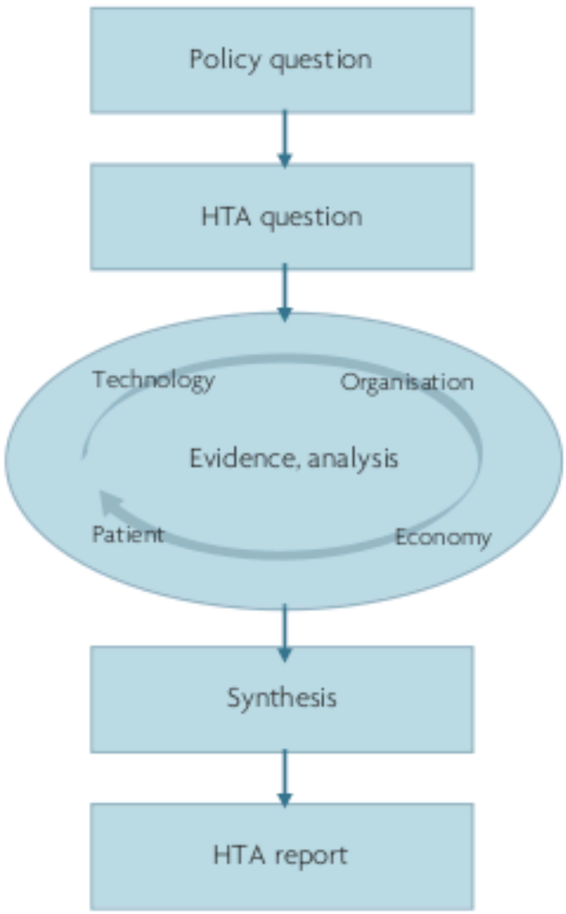


Illustration 4.3: The HTA model (Kristensen & Sigmund, 2007)

The process-model of Kristensen & Sigmund describes the following steps: defining the policy question (1), defining the HTA question (2), analysis of the elements (3), synthesis of the results (4), and reporting the results (5). The steps are not separated steps in the HTA process, but are interwoven. Kristensen & Sigmund (2007) also used four main elements, but chose a different categorisation: technological elements, patient-related elements, organisational elements and economical elements. (see Illustration 4.3). These main elements are overlapping to a certain extent, because the elements' attributes are using the same data or are depending on each other.
Kristensen & Sigmund (2007) argue that the model is not to be followed slavishly and an HTA is not devalued by concentrating on the elements that are relevant in the specific situation – provided that possible choices by exclusion have been carefully explained.

The decision/introduction-process of technological innovations is essentially about information seeking, allowing (the individual/organization) to reduce uncertainty about the advantages and disadvantages of the innovation (e.g. assessment). The HTA-process model of Poulsen seems most suitable to guide surgeons in this process, because the model of Kristensen & Sigmund focuses more on policy questions. But it still needs to be adapted to make it suitable for the complex character that surgical innovations can have. The adapted model is shown in Illustration 4.4.

Both Poulsen (1999) and Kristensen & Sigmund (2007) have used interesting main elements. A selection of the elements and attributes of Poulsen (1999) and Kristensen & Sigmund (2007) is chosen to develop a HTA framework for surgical innovations.
The main elements important for surgical innovations are: technological elements, patient-related elements, clinical elements, economic elements, organizational elements and user elements. As you can see five main elements are being used; the user element has been added. In the model of Poulsen and Kristensen & Sigmund, the user is vaguely integrated in the organisation element. The user is for surgical innovations an important element in the adoption and diffusion. But also within the assessment the user has an important role: robust, scientific evidence, is not of itself, sufficient to ensure diffusion (Fitzgerald, Ferlie, Wood, & Hawkins, 2002 as cited by Greenhalgh et al., 2005;

Dopson, Fitzgerald, Ferlie, Gabbay & Locock, 2002 as cited by Greenhalgh et al., 2005). The process of establishing the credibility of evidence is interpretative and negotiable. This process is particularly complex in health care where much 'knowledge' is ambiguous and contested (Fitzgerald et al., 2002 as cited by Greenhalgh et al., 2005). Adopters/users are active participants in this. The adoption of surgical innovations is depending on the acceptance by the users and they are the ones to collect the evidence. Another argument in favour of the importance of the user element is that a complex surgical innovation can have great impact on the routines and/or ways of working of the operating team.
Surgical innovations that involve the use of technology are common. They are inherently complex and have an important contextual element. Therefore the technological and organisational elements are important. These elements are to a certain degree depending on each other. Surgical innovations are often introduced in an attempt to improve treatment or enhance institutional productivity. This is represented in the clinical and economic element.

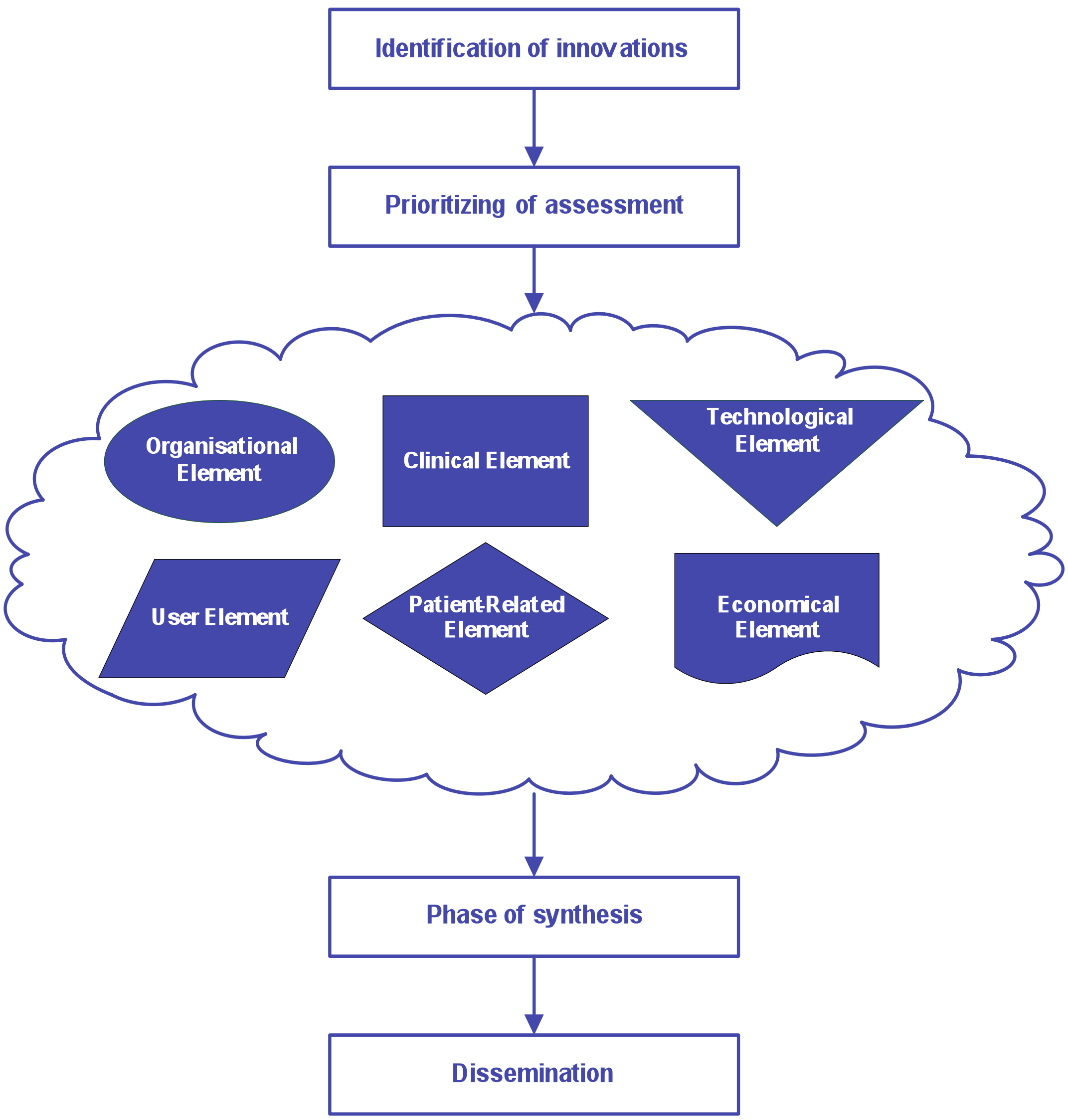


Illustration 4.4: The process of HTA (based on Jørgensen & Danneskiold, 1986 as cited in Poulsen, 1999)

The five elements exist of attributes/variables to assess. The wider literature in organisation and management reveals that innovation attributes that seem positively related to adoption in one organisational study are negatively related in a second and unrelated in still another (Meyer & Goes, 1988 as cited in Greenhalgh et al., 2005). Therefore and because of the broad definition of surgical innovation, the list of attributes to assess needs to be as completely as possible.

Attributes

To define the attributes, several models are used, including the models of Rogers (2003), Poulsen (1999), Douma et al. (2007) and Retèl et al. (2008). The attributes of Rogers (2003) (see Table 4.1 on page 19) are necessary but not sufficient to assess complex innovations as surgical innovations can be. All attributes of Rogers are included in the theoretical framework (sometimes interwoven with other aspects / using synonyms). Relative advantage is not literally in there, because relative advantage can be seen from different perspectives. The definition of 'relative advantage' must change with the nature of the innovation and the organisation or user. For example costs versus benefits for different stakeholder groups can give opposing results. The elements of the other authors are all included, but sometimes the definitions are adapted to make it more specific for surgical innovations. The attributes/variables with their definition are presented in Table 4.8. The relevancy of the attributes is discussed in the next paragraphs.

The technological elements reflect all specific characteristics of the technology that can influence the adoption decision. It includes, among others, the environmental preconditions. Environmental preconditions can be very complex and/or very expensive which can influence the adoption decision. Environmental aspects also influence the implementation, which is a variable of the organisational element.

The clinical element reflects all the outcomes of the treatment the patient receives. The variables in this element are overlapping to a certain degree. The differences can be found in the degree of evidence ('under average conditions of use' versus 'under ideal conditions of use'). The psychological reaction of the patient to the use of the surgical innovation is not included in the clinical element, because it is not an outcome of the treatment. Therefore it is included in the patient-related element.

The economic element includes efficiency and costs. Efficiency reflects avoiding waste. ‘Costs’ reflects all the financial elements of the surgery: the costs for the hospital and the social costs. The social costs have an interaction with the clinical elements.

The organisational element reflects meso and macro[2] aspects of the adoption/implementation of the surgical innovation. This is an element with a great variety of variables which all can influence or are influenced by the adoption of a surgical innovation. For example, the implementation-strategy can influence the utilisation/diffusion within the organisation. The results of research regarding variables in this organisational element can provide information for future adopters of the surgical innovation.

Ethics and juridical aspects are related to both the organisational element and the patient-related elements. Because the introduction of surgical innovations can vary from minor modifications in surgical technique to expensive, complex and sometimes risky experimental surgery, ethics and juridical aspects are important. These are integrated in the patient-related and organisational element.

2 Micro is concerning the patient and user; meso is concerning the organisation; macro is concerning the environment of the organisation, other organisations or national organisations.

As stated before, the user element is an important element for surgical innovations. The user can 'make' the innovation or 'break' the innovation. Therefore the acceptability is an important variable, which is also depending on the other variables; the acceptance of the innovation will probably be higher when other user-aspects are met.

Depending on the technology at hand, the assessment has to focus on a mix of relevant attributes. All attributes should be taken into consideration for the assessment, but in the actual design, only those are included that are estimated relevant for the particular technology and environmental interaction and phase of diffusion. For surgical innovations, the acceptability of the user and the ethical considerations seem to be the most important aspects. Though, the phase of diffusion also determines which aspects to assess. Some variables require a certain research design and an amount of users/patients to ensure the quality of the evidence, but it is possible to assess innovations in an early phase of diffusion. How to choose a mix of relevant attributes and which research method to use, will be discussed in the following chapters, but first the methodology of HTA in an early stage of diffusion and its advantages and disadvantages will be discussed.

Main Elements	Attributes	Definition
Technological elements	Environmental Preconditions	Conditions of the operation theatre that must exist or be established before the innovation can be implemented; a prerequisite.
	Accuracy, reliability & validity	The condition or quality of being correct, or exact; freedom from error or defect; precision or exactness; correctness.
	Technological complexity	Technological complexity covers the degree of complexity of the design and maintenance.
	Reinvention (Rogers, 2003)	The degree to which the surgical innovation can be / is changed or modified in the process of its adoption and implementation (Rogers, 2003) and diffusion.
	Observability (Rogers, 2003)	The degree to which the results of the surgical innovation are visible to others (Rogers, 2003). The extend to which the impact of the surgical innovation can be made observable to key-stakeholders, decision makers and patients through demonstration projects and similar initiatives.

Table 4.4: Attributes for HTA of surgical innovations (part A).

Main Elements	Attributes	Definition
User elements	Risk of malpractice litigation (Meyer & Goes, 1988)	The concomitant risk of malpractice litigation to the physicians who use the surgical innovation (Meyer, 1985) (health risks, ergonomics, etc)
	Skills (Poulsen, 1999; Douma, 2007; Retèl, 2008)	The skills required to use the surgical innovation (Poulsen, 1999).
	Education – Training (Poulsen, 1999; Douma, 2007; Retèl, 2008)	The training and education that is needed to use the surgical technology (Poulsen, 1999).
	Team performance (Cao & Taylor, 2004; Webster & CAO, 2006; Lai & Entin, 2006)	The influence of the adoption or use of the technology on the operation team performance (teamwork, workflow, communication, etc).
	Job performance (Stahl et al., 2005)	The influence of the adoption or use of the technology on the individual job performance.
	Psychological reactions of the user (Stahl et al., 2005)	The psychological reactions of the users on the adoption or use of the technology (job satisfaction, etc.).
	Complexity of usage - Human-System interaction	The degree to which the surgical innovation is perceived as difficult to use (Rogers, 2003) (user friendliness) due to the interaction between the new technology and the user (human-system interaction).
	Acceptability	Acceptance and use of technology by users (Venkatesh et al., 2003). The acceptance of the innovation will be higher when other user-aspects are met.

Table 4.5: Attributes for HTA of surgical innovations (part B).

Main Elements	Attributes	Definition
Organisational elements	Adoption (Retèl, 2008) - Diffusion – Dissemination (Poulsen, 1999; Douma, 2007; Retèl, 2008)	Rate of diffusion or the spread or adoption of the technology and the consequences upon the organization and society (Poulsen, 1999) – inter-organizational. Including rejection and discontinuance of adoption/diffusion.
	Implementation (Douma, 2007, Retèl, 2008) – Assimilation	Implementation strategies used and it's effect on the adoption and use of the technology – intra-organizational (e.g. implementation complexity - The number of response barriers that must be overcome for the technology to be successfully implemented).
	Characteristics of environment (Meyer & Goes, 1988)	The environmental characteristics that influence the success of the innovation (demographic aspects, political aspects, etc) (Meyer & Goes, 1988).
	Characteristics of organisation (Meyer & Goes, 1988)	Organisational size en structural complexity that influence the success of the innovation (Meyer & Goes, 1988) (size, structural complexity, (de)centralisation, innovativeness, leadership, etc)
	Accessibility – Equity (IOM, 2001; Poulsen, 1999)	The amount of patients (and their sociological characteristics) that has access to the technology determined by the organizational structure / logistics.
	System-fit / technology integration (Jacob et al) / compatibility (Rogers, 2003)	The degree to which an innovation is perceived to be consistent with the existing values, culture, needs of the organization, organizational structure, routines and logistics (based on Rogers, 2003; Poulsen, 1999; Douma, 2007; Retèl, 2008).
	Juridical aspects (Retèl, 2008)	Juridical aspects of using the technology on the level of the organization.

Table 4.6: Attributes for HTA of surgical innovations (part C).

Main Elements	Attributes	Definition
Clinical elements	Applicability	The degree to which the innovation is capable of or suitable for being put to practical use in the treatment of the relevant patients.
	Indications (Poulsen, 1999)	The criteria for using and not using the technology (Poulsen, 1999) in the treatment of the relevant patients. Inclusion and exclusion criteria for patients to receive the treatment.
	Population affected (Poulsen, 1999; Douma, 2007)	Epidemiological information of the patient population that could use the technology.
	Utilization (Poulsen, 1999)	The frequency of usage of the technology by the relevant patients (Poulsen, 1999).
	Effectiveness (IOM, 2001; Poulsen, 1999)	The benefit of the surgical innovation under average conditions of use (Poulsen, 1999).
	Social outcomes / Social-environmental impact (Poulsen, 1999; Douma, 2007)	The implications of a surgical innovation for social and legal values, and relationships (IOM, 2001) - "Does the use of the technology lead to changes in a patient's values or social relationships?" The outcome of a treatment measured in Quality of Life (QOL).
	Safety (IOM, 2001; Poulsen, 1999; Meyer & Goes, 1988)	The relatively invariant risk of injury or death to the patient (Meyer & Goes, 1988) measured under ideal conditions of use.
	Efficacy (Poulsen, 1999)	The capacity for producing a desired result or effect to individuals in a defined population from a health technology applied for a given model under ideal conditions of use (Poulsen, 1999).

Table 4.7: Attributes for HTA of surgical innovations (part D).

<table>
<tr><th>Main Elements</th><th>Attributes</th><th>Definition</th></tr>
<tr><td rowspan="2">Economic elements</td><td>Efficiency (IOM, 2001; Poulsen, 1999)</td><td>Avoiding waste, including waste of equipment, supplies, ideas, time (for patient and caregiver) and energy (IOM, 2001).</td></tr>
<tr><td>Costs (Poulsen, 1999)</td><td>Three types of costs can be measured:
The direct running costs related to the technological application.
The necessary capital costs to invest in a technology.
The indirect costs related to the use of the technology.
The analysis of these costs can be from the perspective of the financial costs of the hospital, or the social costs. (Poulsen, 1999)
The following relationships of costs with other aspects can be measured:
Cost-effectiveness (Poulsen, 1999; Douma, 2007; Retèl, 2008): The incremental costs of the technology compared with the incremental health effects (life years saved, days of morbidity avoided, QOL) (Poulsen, 1999).
Cost-utility (Poulsen, 1999): The incremental costs compared with the incremental health improvement (QALY's) (Poulsen, 1999).
Cost-benefit (Poulsen, 1999): All costs and benefits are valued in monetary terms (Poulsen, 1999).</td></tr>
<tr><td rowspan="3">Patient Related elements</td><td>Patient-related juridical aspects (Retèl, 2008)</td><td>Juridical aspects of using the surgical innovation on the level of the patient (Retèl, 2008).</td></tr>
<tr><td>Ethics (Poulsen, 1999; Douma, 2007; Retèl, 2008)</td><td>Societal norms and morals (Poulsen, 1999) - “Would it be ethically desirable from the patient and society perspective to use the surgical innovation?”</td></tr>
<tr><td>Psychological reactions (Retèl, 2008)</td><td>The patients' (and its social system's) perspective on using the surgical technology (e.g. anxiety, acceptability, patient centeredness) (Poulsen, 1999) - “Would the patient (and its social system) accept the technology used in the surgery?” or “With the use of the technology, can the care (still) be respectful and responsive to individual patient preferences, needs, and values?”</td></tr>
</table>

Table 4.8: Attributes for HTA of surgical innovations (part E).

4.3.2 HTA in early phase of diffusion

Some new technologies have clearly improved health and reduced costs, but others have not. Evidence-based medicine and HTA have put a higher demand upon the need to document the impact of new and existing health technologies. Especially the group of medical devices seems to be put on the market early with the possibility of an uncontrolled and fast diffusion in the health care sector (Poulsen, 1999).

Timing of HTA is very important. Technologies may be assessed at different stages of diffusion and maturity. An assessment is the most reliable when the technology is used in routine basis. From an ethical perspective and an economic perspective this cannot be performed. Another problem is to convince care providers to discard an intervention or technology once it has been adopted in clinical practice. Therefore, the earlier a technology is assessed, the more likely its diffusion is to be rationalized (Poulsen, 1999). This is also called the 'Collingridge dilemma'. The Collingridge dilemma is a methodological quandary in which efforts to control technology development face a double-bind problem (Collingridge, 1980):

- an information problem: impacts cannot be easily predicted until the technology is extensively developed and widely used.
- a power problem: control or change is difficult when the technology has become entrenched.

However, the problem at an early phase of diffusion is the lack of information and the uncertainty of this early information with the risk for decision-makers of making a decision-error.

The decision-maker can, based on the theory of statistics, make two types of errors. A Type I decision error is to recommend an unfavourable technology, which is followed by rapid diffusion and later overuse of the technology. A Type II decision error is to reject a favourable technology and take actions to prevent or slow down the diffusion. Both decisions can have severe health and economic consequences. A major objective for decision-makers should be to minimize them (Poulsen, 1999). When deciding upon a proper timing, a dilemma exists between the decision-makers' wish for early assessment prior to widespread diffusion and the problem of reliability and uncertainty of information available early in the diffusion.

Early HTA can be seen as a corner stone in decision-making to inform decision-makers about the evidence and consequences of the adoption of new technologies, before a widespread diffusion occurs. Especially with respect to the medical devices and medical procedures, which are adopted early in the life cycle and often before any assessment, there is a need of early assessment. An early (preliminary) assessment can then assist in the decision-making, whether the technology should be adopted, or whether resources should be devoted to do additional research (Poulsen, 1999).

Next to the dilemma of uncertainty of information, the same problem occurs as with the diffusion theory of Rogers (2003). The S-shaped pattern of the cumulative adoption curve of Rogers only occurs if the population is fixed and the influence of the innovation stays constant over time ('ceteris paribus'). Such an unrealistic 'ceteris paribus' is created, when performing a Randomized Controlled Trial (RCT). HTA studies that assume the technology and its environment to be stable, are likely to produce outdated evaluations of the quality of the technology. The results are outdated by the time the assessment is published (Douma et al., 2007). Especially HTA's performed in an early phase of diffusion. An assessment at that early stage requires structuring the possible scenarios, computing their probabilities and assessing their consequences (Pietzsch & Cornell, 2008). One of the methods to do this is scenario drafting (see 4.4.1 Assessment methods).

Aspects of surgical innovations important to assess in an early phase of diffusion are all technical attributes, the applicability, indications, safety and effectiveness, ethical and juridical aspects, risks of malpractice litigation, complexity of usage and acceptability. It can be presumed that it is possible to measure these attributes in an early phase of diffusion and let the results assist in the decision-making. The technological attributes, like reinvention or accuracy, reliability & validity can even be measured in the development phase. Because surgical innovations can have a very experimental character with high (or unknown) risks, the ethical and juridical aspects need special attention in this phase. The ethical and juridical aspects are highly influenced by the (perceived) safety and effectiveness of the innovation.

Nowadays technologies / innovations are very often modified as they are disseminated. The focus of HTA studies needs to shift from studying the quality of a new technology to optimizing the technology's quality and effectiveness under dynamic circumstances. Therefore a flexible, iterative and ongoing assessment is necessary. Douma et al. (2007) advocates for the methodology of Constructive Technology Assessment (CTA) to be helpful for HTA in general.

4.3.3 Constructive Technology Assessment

Because of the increasing complexity of technologies and the dynamic character of development, HTA has become more complex. Battista (2006) even states that the complexity of HTA has increased so much that input from other research fields is necessary to maintain its relevance (as cited by Douma et al., 2007). Poulsen (1999) advocates for an iterative and ongoing approach to assessment, because technologies / innovations nowadays are very often modified as they are disseminated. This is especially the case in surgical innovations.

A few methods claim to cope with the dynamic circumstances of technologies. Bayesian methods are a good example and are widely used, but a basis of data is required. This requirement makes application in the innovation and early adopter phase less likely. Constructive Technology Assessment (CTA) is a dynamic way of assessment that starts before the new technology has been introduced into clinical practice and goes on during the phases of diffusion.
Probably CTA can fulfil the objectives to cope with the dynamic character of development and be an iterative and ongoing approach to assessment starting in the innovation and early adopter phase (Douma et al., 2007; Retèl et al., 2008).

In the mid 1980s (and starting in the Netherlands) a variant of Technology Assessment (TA) was developed which proposed to include TA already in the design and development phase of new technology. This proposal to let TA be part of the construction of technology was called Constructive Technology Assessment (CTA) (Daey Ouwens et al., 1987 as cited by Rip, 2001). CTA is a way to overcome the so-called Collingridge Dilemma (Collingridge, 1980) (see Collingridge dilemma on page 32).
The impact of the introduction of new technologies cannot always be foreseen. Most of these effects become manifest during and after introduction into more general use. The possibilities for correcting them (if necessary) by adjusting the technology are limited. By the time the negative impacts are recognized, the technology is already firmly embedded in sectors, institutions and practices. Study periods from submitting the design to presentation of the results of the research can easily take six to seven years. Thus, a dilemma between control and entrenchment (Rip, 2001).
When using CTA, the technology and the social conditions co-evolve in the same movement (Rip and Kemp, 1998 as cited by Rip, 2001), and assessments of various kinds occur all the time. The challenge is to prejudice these assessments in the right direction – as part of an open-ended learning process about what the “right” direction could be (Rip, 2001). The shaping of technology, of its properties and impacts extends beyond the development stage into adoption, implementation and

wider use. Innovation and development does not stop when diffusion starts. This is equal with the attribute “reinvention” of Rogers (2003) (see table 4.1, page 15).

Douma et al (2007) describe the methodological possibilities to use CTA in the health care sector as a complementary approach in addition to HTA. Douma et al advocate that CTA not only considers the dynamics of the technology, but also the dynamics of other domains, such as practice organization and financing, patient reactions, and juridical and ethical aspects (Berg & Van der Grinten, 2004). The elements to assess can be the same as in HTA, but take the dynamic circumstances into account.

Because of the dynamic character of CTA that goes along with the dynamic character of the technology, different approaches are being used. A new technology that is only being used by the innovators will need a different assessment approach than a technology that has been used by the early majority. For example, Randomized Controlled Trials (RCT's) can only be performed when sufficient numbers of patients can be included, which means the technology needs to be used in a regular basis.
Therefore, CTA uses different diagnostic methods in different phases of diffusion. Diagnostic methods of CTA include traditional social science techniques and also socio-technical mapping techniques to identify the past and possible future scenarios of technology dynamics (Douma et al., 2007).

According to the above, one could argue that CTA is more effective than traditional HTA, because of its close involvement with technology, and the start at early stages. Its ambition is, however, limited to modulating ongoing processes and to be part of open ended learning processes. This is realistic, but not conclusive. Other varieties of HTA should complement CTA (Rip, 2001).
Though, taking the above into consideration, CTA seems a possible solution for the problem of 'ceteris paribus' (see page 32), because CTA starts before the new technology has been introduced into clinical practice, goes on during the phases of diffusion, and is a dynamic way of assessment. And the assessment methods of CTA that can be used in an early stage of diffusion to predict possible future scenarios, can maybe decrease the problem of uncertainty of information.

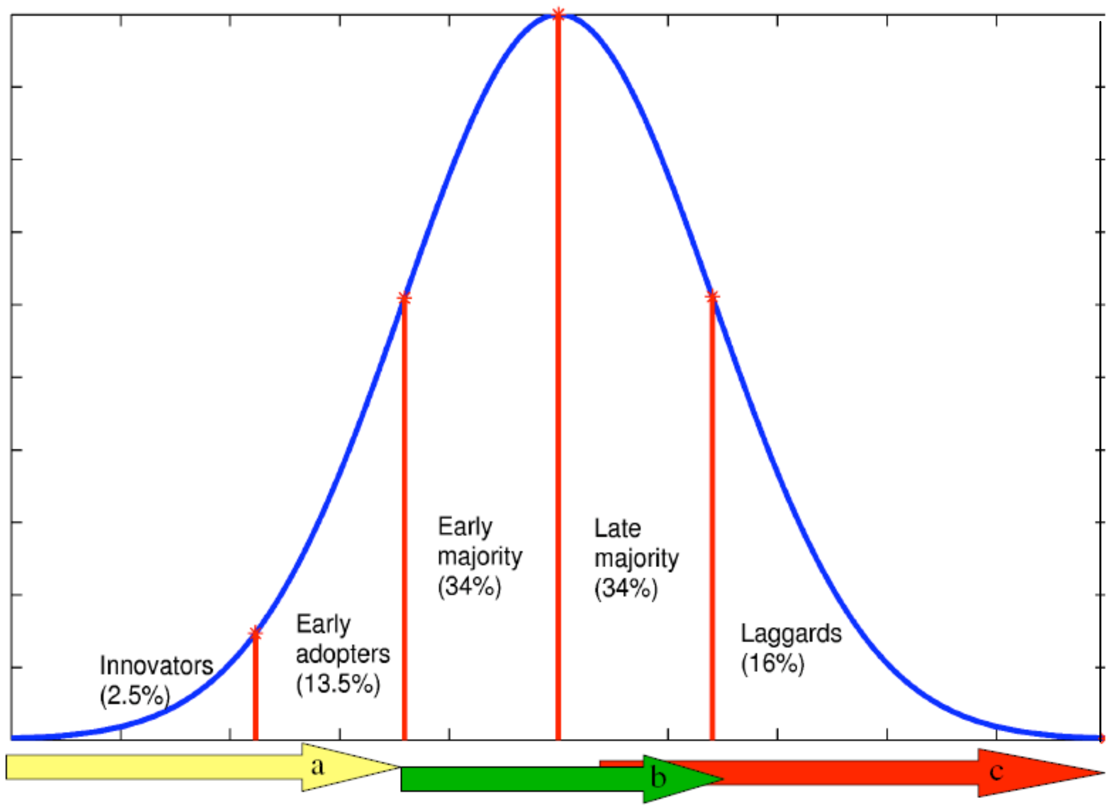
4.4 *Assessment methods and appraisal of the evidence*

The decision to adopt an new intervention, such as a new medical technology, should depend on evidence. As stated before, new technologies are even adopted despite poor evidence (Meakins, 2002; Danjoux, et al., 2007), probably because evidence can be difficult, time-consuming, and expensive to collect. And the true performance of an intervention typically remains uncertain (to a certain degree) even after evidence has been collected. This residual uncertainty makes it necessary for deciding when evidence is adequate to adopt an innovation as the new “golden standard”. A second question is whether additional evidence should be gathered to further reduce uncertainty and, if so, how this should be collected. In this section first the traditional approaches are described with their pro's and cons. Then alternative approaches (decision-analysis and value-of-information analysis) are being discussed.

4.4.1 Assessment methods

When starting a CTA/HTA a systematic literature review has to be done to find out which documented knowledge is already available. If there is not sufficient documented knowledge, research should be implemented to obtain such knowledge, and the decision-making has to be based on expert assessments until a better documented basis becomes available (see illustration 4.5). When not performing a systematic literature review, traditional research is implemented, which may be

unnecessary, expensive and time-consuming.
The literature on technology assessment methods can be divided in diagnostic and intervention methods. Diagnostic methods are used to assess the quality of the innovation. Intervention methods are used to influence technological development and application. The traditional clinical and economical research designs are used in HTA. HTA does not refer to intervention methods. Diagnostic methods of CTA include traditional social science techniques and also sociotechnical mapping techniques to identify the past and possible future scenarios of technology dynamics. Intervention methods in CTA are action techniques, including awareness initiatives, controlled experimentation, consensus conferences, and dialogue workshops, to influence technological development and application (Douma et al., 2007).



a Performing future scenarios of technology dynamics to inform and advice decision makers about further research and development (R&D) and (early) adoption of the health technology.
b Performing studies that acquire a sufficient number of patients and users to inform users and decision makers about the impact of the health technology.
c Assessment of health technology in routine practice setting.

Illustration 4.5: Aims of assessment in the phases of diffusion.

To take the dynamics of the technology and all other elements into account, CTA uses different diagnostic methods in different phases of diffusion. In an early stage the assessment aims to inform and advice decision makers about further research and development (R&D) *(see arrow **a** in Illustration 4.5)*. Also possible future scenarios of technology dynamics can be performed in this stage to inform and advice decision makers about (early) adoption of the health technology *(see also arrow **a**)*. In a later stage studies that acquire a sufficient number of patients (like Randomized Controlled Trials (RCT's)) can be performed *(see arrow **b**)*. In the final stage assessment of health technology in routine practice setting can be assessed (*see arrow **c***). In every separate phase the dynamics of the technology are taken into account (Douma et al., 2007). I have combined the aims of assessment with the technology diffusion theory of Rogers (2003) and its categorization of adopters in *Illustration 4.5*.

Next to the traditional research strategies, Rip (2001) describes two generic CTA intervention strategies: Technology Forcing and Strategic Niche Management. Technology Forcing starts in the development phase. It is the generalisation of technology forcing through (government) regulation: instead of traditional (H)TA attempting to anticipate to yet unknown impacts (positive and negative), here the desired impacts are specified beforehand and the technology is left open (to some extent). The basic idea is that technology actors are challenged to develop technologies that will fulfil the stipulated impacts.
Strategic Niche Management emphasizes the quality of learning. It is the orchestration of the development and introduction of new technologies through a series of experimental settings or niches. In these experimental settings different categories of actors are brought together: the designers, future users, governmental agencies and CTA agents. The CTA agent engages in facilitating and modulating the interactions between the other categories of actors. In the interactions the actors learn from the perspectives and desires of each other; the technical side of the design, the needs and requirements of the user and the cultural and political acceptability of technology in development. Subsequently, graded introduction of the new technology is to be realised.
Rip and Te Kulve (2008) mention a third intervention strategy, namely Socio-Technical Scenario Drafting (also called roadmapping). For a lot of surgical technologies, most of the envisioned applications are still in the realm of fiction, in the sense that they are not there yet, and that it is not clear whether they will ever be realized. Their eventual impacts are even less clear. This fictional character requires the use of scenarios, in particular socio-technical scenarios which capture ongoing dynamics and develop implications for what might happen. In CTA, socio-technical scenarios are not just creative exercises showing possible futures, but they also embody and further articulate emerging patterns in interactions, up to paths that actors tend to follow. Social-Technical Scenario Drafting is a soft intervention, attempting to modulate ongoing socio-technological developments, realize better technology in a better society, at least by making them more reflexive.

Strategic Niche Management, Social-Technical Scenario Drafting and other strategies that emphasize learning and reflexivity are productive in assuring quality control, but do not guarantee the nature and direction of the quality. The strategy of Technology Forcing, on the other hand, starts out by specifying the nature of the quality to be realized - and then runs the risk that the technology falls short (Rip, 2001). Every assessment strategy has his benefits as well as his doubts. It is important to weigh the pros and cons to choose the best assessment strategy for that specific study. The next paragraph will discuss methods that can help to choose the best strategy.

4.4.2 Appraisal of the evidence

Traditional approaches to the evaluation of innovations in health care rely both on predetermined criteria for assigning weights to different types of evidence (evidence hierarchy) and on long-established methods of statistical hypothesis testing. Qualitative research and case study methods are described as the lowest in the evidence hierarchy. Randomized Controlled Trials (RCT's) have been the favoured form of evidence. This hierarchy of evidence developed by Sackett (1986) (see Table 4.9) has provoked much unresolved controversy about the kind of evidence that is actually most relevant to practice; for example, controlled trials often restrict the kind of patients recruited, whereas cohort studies better reflect normal patterns of patient management. RCT-based evidence on its own is not sufficient for making decisions about the adoption of the innovation (Claxton, Cohen & Neumann, 2005). RCT's do not take implementation issues into consideration and the method is time-consuming and not dynamic (see chapter 4.3.3 Constructive Technology Assessment). In the case of cancer treatment: suppose a well-conducted observational (non-randomized) study suggests that a treatment is effective, does it then make sense to withhold this treatment from the population until a 'proper' RCT can be conducted?

Other methods that are used frequently are statistical hypotheses testing methods. The use of statistical hypothesis testing to interpret study results can also lead to suboptimal decisions (Claxton, Cohen & Neumann, 2005). In the context of medical technologies, this refers to the assessment of the hypothesis, based on RCT data, that the new technology offers an improvement in health outcomes relative to the status quo. This comparison is complicated by 'noise' introduced by natural variation across individuals; the significance of the statistical hypothesis testing is depending on the amount of patients in the RCT study. When the amount of patients is not sufficient, which makes the significance of the results of the RCT low, this can lead to different decisions. A conventional decision maker would reject adoption, whilst an proponent of the innovation would decide to gather additional evidence. The problem with the conventional approach is that the adoption criteria, like the exclusive reliance on RCT studies, are not linked to broader concerns (Claxton, Cohen & Neumann, 2005).

Oxford's level of evidence[3]	Therapy/Prevention, Aetiology/Harm	Economic and decision analyses
1A	SR (with homogeneit*) of RCTs	SR (with homogeneity*) of Level 1 economic studies
1B	Individual RCT (with narrow Confidence Interval)	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1C	All or none[‡]	Absolute better-value or worse-value analyses[†]
2A	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of Level >2 economic studies
2B	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2C	"Outcomes" Research; Ecological studies	Audit or outcomes research
3A	SR (with homogeneity*) of case-control studies	SR (with homogeneity*) of 3b and better studies
3B	Individual Case-Control Study	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies[§])	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Table 4.9: Oxford's Levels of Evidence (OLE). (Adapted from: http://www.cebm.net/index.aspx?o=1047)

Abbreviations: SR = Systematic Review, RCT = Randomized Controlled Trial

3 Oxford Centre for Evidence Based Medicine Levels of Evidence (May 2001)

□ By homogeneity is meant a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.

‡ Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.

† Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.

§ By poor quality cohort study is meant one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study is meant one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

Claxton, Cohen and Neumann (2005) argue that decision analysis and value-of-information (VOI) analysis should be used to determine whether an innovation should be adopted, whether additional evidence to further inform that decision is worth gathering, and what kind of information is of the greatest value.

Techniques from the field of decision analysis (Markov modelling, Bayesian statistical decision analysis) formalize the question of whether to adopt or reject an innovation. Graphical representation of decision analysis problems commonly use influence diagrams and decision trees. Both of these tools represent the alternatives available to the decision maker, the uncertainty they face, and evaluation measures representing how well they achieve their objectives in the final outcome. Uncertainties are represented through probabilities and probability distributions. The decision maker's attitude to risk is represented by utility functions and their attitude to trade-offs between conflicting objectives can be made using multi-attribute value functions or multi-attribute utility functions (if there is risk involved). Decision analytical tools such as Multi-Attribute Value Models, Bayesian Probability Networks, and Decision Trees are commonly used (Alemi & Gustafson, 2006). Common metrics include quality-adjusted-life-years (QALY's) saved/lost and monetary equivalents (Claxton, Cohen & Neumann, 2005).
Note that decision analysis does not prejudge evidence as acceptable or unacceptable based on the level of evidence, although the type of evidence will help determine its influence on an adoption decision. However, this influence depends on what the evidence reveals in a particular circumstance, not on a pre-specified weight assigned to different types of evidence.

In addition to deciding whether to adopt or reject an innovation, the decision maker must also decide whether the gathering of additional information is warranted. According to Claxton, Cohen and Neumann (2005) VOI techniques are useful. VOI analysis evaluates the extent to which new evidence might improve expected benefits by reducing the chance for error and compares that improvement with the cost of the information. Thus, VOI is the amount a decision maker would be willing to pay for information prior to making a decision.
In general, VOI analysis prescribes the gathering of more information when the following conditions hold (Hammit & Cave, 1991 as cited by Claxton, Cohen & Neumann, 2005): (1) The research has the potential to identify a new optimal alternative intervention; (2) there is likely to be a large advantage of the new optimal intervention compared with the alternative now viewed as optimal; and (3) the cost of gathering new information is not too large compared to its value. Each of these criteria is discussed below.

(1) *The potential to identify a new optimal alternative.* If the decision maker is already reasonably sure about which alternative is optimal, then gathering new information has little chance of affecting the decision. In this case there is little reason to gather information.
(2) *The possibility of a large advantage with the new alternative.* Switching from the current intervention to the new alternative has to outweigh the cost of gathering the information. If the advantage of the new alternative is at best limited, then gathering new information has no additional value.
(3) *The cost of gathering the information.* Gathering additional information involves resource expenditures and time. In the interim, the decision maker can only use the information that available at that moment. Suboptimal decision making in the interim may subject patients to inappropriate treatment. In some cases, it may make more sense to pursue somewhat less rigorous if that information can be gathered more quickly.

These techniques cannot only help to determine whether additional research is worthwhile, but can also help to determine how research efforts should be prioritized. For example, suppose that it is possible to either study the efficacy of a new treatment or to gather information about the progression of the condition it addresses. It is possible to quantify separately the extent to which research in each of these two areas is likely to improve decision-making. In this way, given the decision maker’s objectives, the most 'important' research can be identified.

According to Claxton, Cohen & Neumann (2005) decision analysis and VOI analysis allow the decision maker to use all of the information available to determine the best way to proceed. However, in doing so, these techniques keep track of the uncertainty underlying the prescription and help the decision maker identify what additional evidence should be collected.
These methods are likely to fit within the paradigm of HTA and CTA, especially for the early adopter and early majority phase. It can probably help the early adopter to decide which additional research they have to do and it can help the group of early majority to make a decision about the adoption of a new medical technology with less uncertainty. Unfortunately, the applicability of these methods cannot be evaluated during this master thesis, due to a lack of knowledge to perform these analyses, no available case study and a lack of time to perform a prospective study.

5. The DaVinci Surgical System: A case-study

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Introduction

In this master thesis the DaVinci Surgical System (DVSS) is used to evaluate the completeness of the list of variables (Table 4.8 on page 27-31) and the current use of the assessment methods and research designs of the theoretical framework. The DVSS is introduced in 1999 by Intuitive Surgical located in Sunnyvale, California. In 2000 the first DVSS was implemented in the Netherlands, the University Medical Centre Utrecht. In 2008 the sixth DVSS has been adopted in the Netherlands. The DVSS is still in an early phase of diffusion, which makes it a good example to evaluate the theoretical framework. This case-study gives insight in the aspects that have been assessed, the assessment methods that have been used, and the quality of the evidence.

5.1 Background

Illustration 5.1: The DaVinci Surgical System. © 2009 Intuitive Surgical, Inc.

Robotic-assisted surgery

The word robot is derived from the Czech word 'robota', meaning 'forced labour'. Karel Čapek introduced and made popular this word which is now frequently used internationally. The word robot was first used in his play 'R.U.R.' (Rossum's Universal robots) in 1921 where a scientist invents humanlike machines which later dominate the human race and threaten it with extinction.

The earlier surgical robots were used in neurosurgery and orthopaedic surgery. The computer provided anatomic landmarks. Contemporary medical robotic systems used in surgery usually consist of a computer and a mechanical device to carry out the task. The systems are provided with or without an image acquisition module. As the complexity of laparoscopic surgery developed, the robots evolved to more complex systems. Now two categories exist (Sim, Yip and Cheng, 2006):

- offline robots (completely automated with pre-programmed motion planning)
- online robots (interactive systems which rely on continuous input in real time)
    - endoscopic manipulators (endoscopic camera-holders with positioning functions)
    - master-slave robotic systems (a computerized surgical console (master unit) linked to an endoscopic manipulator with several robotic arms for instrument manipulation (slave unit))

Illustration 5.3 shows the development tree of robotic surgery.

The DaVinci Surgical System

The DaVinci Surgical System is a master-slave robotic system. The DaVinci Surgical System uses powered control elements in the form of a patient-side cart with three or four robotic manipulator arms linked to a surgeon console, a 3D HD vision system and EndoWrist® instruments (see Illustration 5.2). The design of the EndoWrist instruments exceeds the natural range of motion of the human hand. The digital control of instruments through the console makes digital filtration of movement tremors and motion scaling possible and refine the surgeon’s hand movements.

With conventional laparoscopy, the surgeon is standing and must look up and away from the instruments, to a nearby 2D video monitor to see an image of the anatomy. The surgeon must also rely on the assistant to position the camera correctly. With using the DaVinci Surgical System the surgeon operates from a seated position using the binocular viewport to watch the 3D images which he can control. The surgeon's arms are supported while handling the instruments.

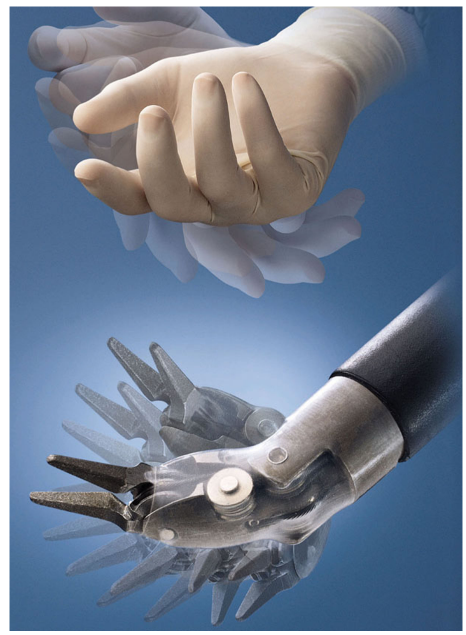

Illustration 5.2: EndoWrist® instruments. © 2009 Intuitive Surgical Inc.

The DaVinci Surgical System was developed to fulfil the need for more precise, tremor-free dissection in the thorax in cardiovascular procedures. This system was later adapted for other procedures in urology, general surgery and now gynaecologic and paediatric surgery. The description of the advantages of the DaVinci Surgical system seems promising. The HTA-framework is used to assess the impact of the DaVinci Surgical System.

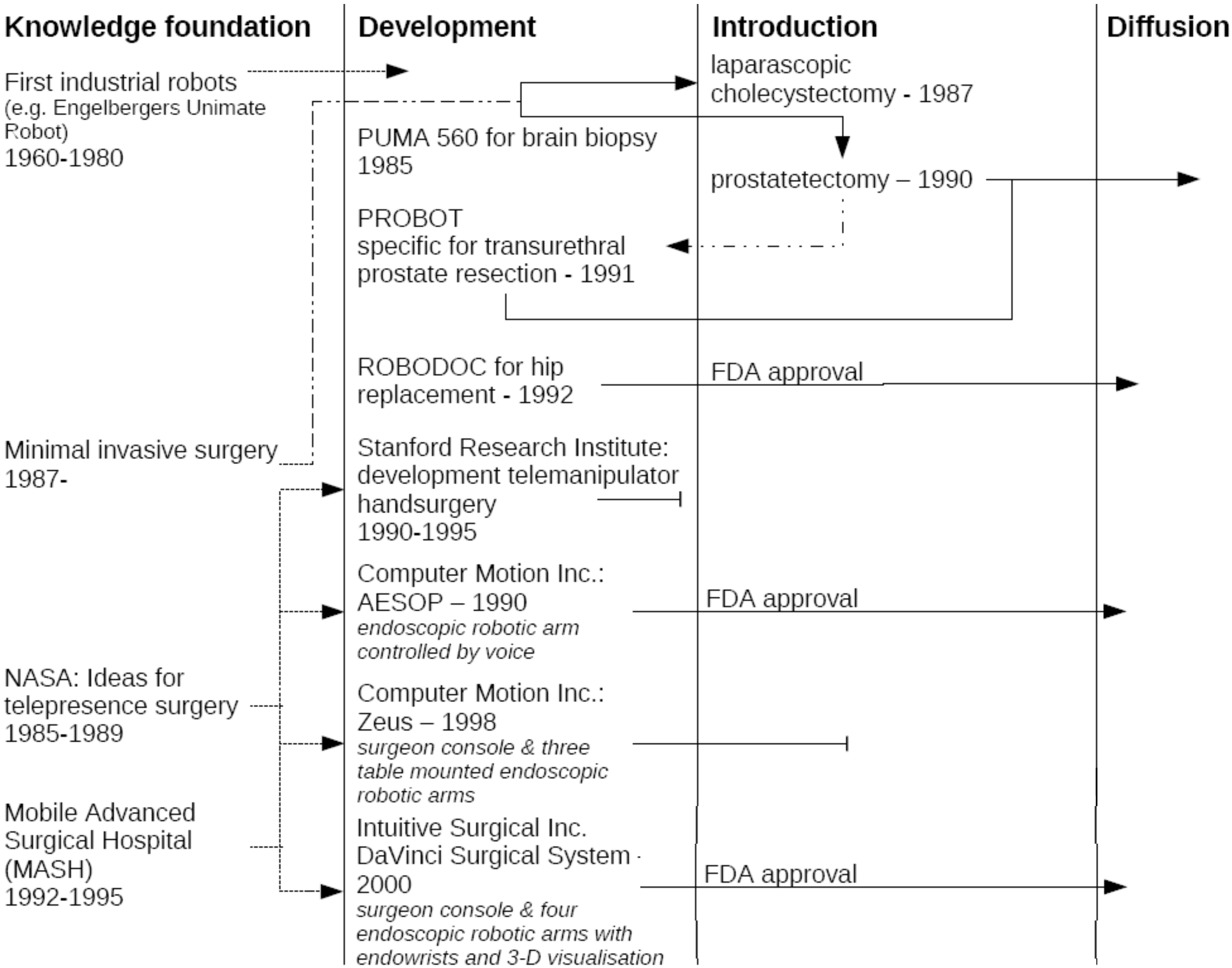

Illustration 5.3: Development tree robotic surgery

5.2 Method

Semi-structured interviews

Semi structured interviews are used to evaluate the completeness of the list of variables, the relevancy of the individual variables and the assessment methods used in the Netherlands. The inclusion criteria for the interviews were:

- persons involved in the introduction process of the DVSS in a hospital in the Netherlands
- persons involved in research regarding the impact of the DVSS.

Most hospitals that adopted the DVSS mention this on their website, which made it easy to locate the hospitals and surgeons. Also the hospital-locator on the website of Intuitive Surgical was helpful (www.intuitivesurgical.com). The hospitals received an invitation by e-mail.

5 surgeons from 4 different hospitals were willing to cooperate. The hospitals were all academic hospitals and can be described as innovative. A topic-list was used to structure the interviews (see Appendix 1.). The interviews started with open questions regarding the introduction process and the research concerning the impact of the DVSS. The open questions were followed by closed questions lead by the list of variables (**Error! Reference source not found.** on page 27-31). Every variable was mentioned to check if they had performed research regarding that variable. This method also gave insight in the completeness of the list and the correctness of the definitions.

A few modifications were made in the list of attributes after performing the first interview. During the interviews it became clear that a new attribute needed to be added: applicability. The attributes 'complexity' and 'human-system interaction' and their definition were adapted to 'technological complexity and 'complexity of usage – human-system interaction', because the attributes were too similar. For the same reason the attributes 'social outcomes' and ‘social-environmental impact’ were combined. After the modifications the attributes were clearly defined, except for the attribute 'observability'. This is a difficult attribute to understand and to measure.

Literature Review

Next to the interviews, a review to determine the aspects that have been assessed for the DVSS and the research methods used in the assessment was performed. The search engine CombiSearch provided by the Twente University was used. The search terms used are the DVSS or robot-assisted surgery. Other search terms have been based on the surgical specialties, the list of main elements and their variables (Table 4.4 on page 27-31). The complete list of search terms can be found in Appendix 2. Articles concerning research using the DVSS as their main subject were included. Articles were excluded if there was a report with a higher level of evidence regarding the same subject.
The articles were assessed with use of CBO appraisal lists (Kwaliteitsinstituut voor de Gezondheidszorg CBO, 2006):

- Review of Randomized Controlled Trials (RCT’s).
- Review of Diagnostic Studies.
- Review of Observational Studies.
- RCT’s.
- Diagnostic Research.
- Patient Control Research.
- Cohort Research.
- Qualitative Research.

The McMaster appraisal lists (Law, Stewart, Letts, Pollock, Bosch,& Westmorland, 1998a; Law, Stewart, Letts, Pollock, Bosch,& Westmorland, 1998b) were used for appraisal of articles describing the following research designs:

- Singel Case Design
- Before-After Design
- Clinical Controlled Trial (CCT)
- Cross Sectional Design
- Case Study

Analyses

The Oxford Centre for Evidence Based Medicine Levels of Evidence (Oxford's Levels of Evidence = OLE) (Phillips, Ball, Badenoch, Straus, Haynes, & Dawes, 2001) are used to score the results and define the research methods. If alternative methods are used, they are mentioned separately, because they do not fit in the OLE's list. Also a score for positivity of the results / conclusion was given (see Table 5.1). The level of positivity of the results can be positive, neutral, arguable, or negative. Each score is represented by a colour. Blue represents a positive result, green is a neutral result, orange arguable and red represents a negative result.
The interviews were prepared for analyses and analysed by performing the following steps: First all interviews have been processed to a text file (script verbatum). Then all text with no relation to the DVSS or HTA has been removed. After that, every interview has been subdivided into fragments and encoded. These fragments with their codes were then categorized by variable and main element. By using this method of structuring it was possible to combine the responses and find connections.

Then the results of the review and interviews were compared with the list of variables. This has resulted in a table regarding the OLE, the degree of positivity and the results of the studies for each attribute of the theoretical framework. With use of this table it was possible to see which variables were studied and which research designs were applied.

Positive results	++
Neutral results	+
Arguable results	-
Negative results	--

Table 5.1: Degree of positivity of the results (p)

5.3 Results

The joint results of the interviews and the systematic review can be found in Appendix 3. Table 5.2 presents a summary of the results. The technological, organisational and user elements reflect the general use of the DVSS. The results of studies related to the clinical, economical and patient-related elements are explicit for the specific surgical specialties that use the DVSS; cardiac applications, general applications, thoracic applications, urologic applications, gynaecologic applications and paediatric applications.

General use

Technological element

The results of the literature review regarding the technological elements are based on 11 studies. Most studies reflect the reinvention of the DVSS. Most studies were case studies, expert opinions or experimental studies. The highest level of evidence (HOLE) was a case control study (Level of Evidence 3B) regarding the added value of haptic feedback. More research is necessary to conclude if haptic feedback has an additional value. An experimental technical study was performed in 2006 to determine the intrinsic accuracy of the DVSS. Another study regarding the variable 'accuracy, reliability and validity' described a failure of the DVSS. Reports concerning the other variables within the technological element were not found.

The results of the interviews confirmed that reinvention is an important variable to study. The respondents were disappointed about the initiatives of Intuitive Surgical for reinvention. The interviews also revealed that 'environmental preconditions' is an important variable for surgical innovations and in particular the DVSS. The use of a surgical technology is in a specific environment, what makes this aspect important. Regarding the DVSS, the environmental preconditions should have had more attention, because problems have occurred during the implementation phase in hospitals in the Netherlands. The storage of the system, power supply requirements, and the dimensions of the system gave rise to problems for the implementation of the DVSS.

From the literature review and the interviews can be concluded that only the variables 'accuracy, reliability and validity' and 'reinvention' are studied. Reinvention remains an important variable for future research, because reinvention can enhance the utilization and applicability possibilities. There are initiatives for reinvention studies in the Netherlands. Another important future research question concerns the environmental preconditions: “How should the DVSS ideally be integrated in the operation theatre?”

Organisational element

Little research has been performed regarding the organisational element. Intuitive Surgical reports the diffusion data online, but no research regarding the driving forces for adoption or other organisational research has been reported. Other results in this element are from the semi-structured interviews.
According to the respondents the implementation of the DVSS would be a good research subject for the future; a study regarding the implementation strategies used and the problems/successes that have occurred. The environmental characteristics were perceived as the driving force in the adoption decision (strategic management). In general, the organisational elements were not very interesting according to the respondents. There is a bias in this result, because all respondents were surgeons who probably want to have the best treatment for their patient.
In my opinion the organisational element is important for surgical innovations. For instance, the dissemination and use of the surgical technology cannot be optimized without the use of adequate implementation strategies.

User element

More reports have been found for the user element, especially the variables 'risk of malpractice litigation' and 'education-training'. The results of these variables were highly positive with a relative high level of evidence. The job performance was reported in 2 reports. The results were positive, but the level of evidence was low and dated from 2004. No reports were found regarding the skills, team performance, psychological reactions of the user, complexity of usage, or acceptability.

The interviews confirmed that, for surgical innovations in general, the variables 'education' and 'risk of malpractice litigation' are important variables. One surgeon mentioned that the preliminary results of skills necessary to use the technology need to be clear before the early adopter phase. Team

performance was mentioned to be relevant by all respondents; as well for the DVSS as surgical innovations in general. According to the respondents the quality of the surgery is depending on the team performance. Based on the semi-structured interviews it seems that teamplay is an important factor in working with the DVSS. It would be interesting to know what the influence is of teamplay on team performance.
Regarding the job performance, a surgeon mentioned that this is a dangerous variable. "*It is being avoided in this field because it gives information about the performance level of individuals. The consequences of this information are frightening.*"
'Psychological reactions' was the least valued variable. Though, a few surgeons mentioned that due to the increasing presence of technology in the operation theatre the job changes and that a study concerning the job satisfaction would be interesting. Especially after adoption of the DVSS the job of a surgeon changes, because the surgeon is seated in the console, separated from the team. This has not been studied yet. The results of the complexity of usage were a little contradicting; all surgeons declared that the DVSS is user-friendly, but a few mentioned they missed haptic feedback. This is contradicting the results of the literature. Acceptability of the DVSS in relation to the diffusion between different specialities would be a variable interesting to study, as mentioned by one respondent. The robot was developed for cardiac surgery, but was not sufficient accepted. In urology the DVSS made a comeback.

For the user element it can be concluded that the most important elements are 'risk of malpractice litigation', 'team performance', 'complexity of usage' and 'acceptability'. For the DVSS more research is necessary to get insight in the acceptability and its influencing factors.

Main elements	Variables	General use								
		++		+		-		--		YOP of HOLE
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	
Technological element	*Environmental Preconditions*			1	5			1	5	Int.
	Accuracy, reliability & validity	1	5					1	5	2008
	Technological complexity							1	5	Int.
	Reinvention	1	4	1	5	1	3B	2	5	2007
	Observability							1	5	Int.
Organisational element	*Adoption - Diffusion – Dissemination*			2	4	1	5			2008
	Implementation – Assimilation							1	5	Int.
	Characteristics of environment							1	5	Int.
	Characteristics of organisation									
	Accessibility – Equity							1	5	Int.
	System-fit / technology integration / compatibility	1	5							Int.
	Juridical aspects							1	5	Int.
User element	*Risk of malpractice litigation*	3	3B							2007
	Skills			1	5					Int.
	Education – Training	4	2B					1	5	2007
	Team performance	1	5	1	5					Int.
	Job performance	2	5	1	5					2004
	Psychological reactions of the user							1	5	Int.
	Complexity of usage - Human-System interaction	1	5					1	5	Int.
	Acceptability							1	5	Int.

Table 5.2: Summary of the results (1)

Index:

Amount = amount of results.
H OLE = Highest Oxford's Level of Evidence.
Yop of H OLE= Year of publication of article with Highest Oxford's Level of Evidence.

Main elements	Variables	Cardiac surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	3	4							2007
	Indications									
	Population affected[1]									
	Utilization									
	Effectiveness									
	Social outcomes									
	Safety	2	4							2006
	Efficacy									
Economic element	*Efficiency*									
	Costs	1	2 B							2005
Patient-related element	*Patient-related juridical aspects*									
	Ethics					1	5			Int.
	Psychological reactions									

Main elements	Variables	General surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	6	3 B			1	2 B			2007
	Indications									
	Population affected[1]									
	Utilization									
	Effectiveness					2	2 B			2005
	Social outcomes									
	Safety					1	1 B			2005
	Efficacy							1	1 B	2006
Economic element	*Efficiency*	2	1 B			1	1 B	3	4	2007
	Costs							3	1 B	2007
Patient-related element	*Patient-related juridical aspects*									
	Ethics									
	Psychological reactions									

Main elements	Variables	Gynecologic surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	1	3 A							2007
	Indications									
	Population affected[1]									
	Utilization									
	Effectiveness	3	2 B							2008
	Social outcomes									
	Safety									
	Efficacy									
Economic element	*Efficiency*									
	Costs									
Patient-related element	*Patient-related juridical aspects*									
	Ethics									
	Psychological reactions									

Main elements	Variables	Pediatric surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	2	4							2006
	Indications									
	Population affected[1]									
	Utilization									
	Effectiveness	1	3 A			1	2 A			2008
	Social outcomes									
	Safety									
	Efficacy									
Economic element	*Efficiency*									
	Costs									
Patient-related element	*Patient-related juridical aspects*									
	Ethics									
	Psychological reactions									

Main elements	Variables	Thoracic surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	5	4							2006
	Indications									
	Population affected[1]									
	Utilization									
	Effectiveness									
	Social outcomes									
	Safety									
	Efficacy									
Economic element	*Efficiency*									
	Costs									
Patient-related element	*Patient-related juridical aspects*									
	Ethics									
	Psychological reactions									

Main elements	Variables	Urologic surgery								
		++		+		-		--		
		amount	HOLE	amount	HOLE	amount	HOLE	amount	HOLE	YOP of HOLE
Clinical element	*Applicability*	4	4	1	2 A	1	2 A			2007
	Indications			2	3 A					2006
	Population affected[1]									
	Utilization	1	5							Int.
	Effectiveness					4	2 A			2007
	Social outcomes	2	4							In press
	Safety									
	Efficacy									
Economic element	*Efficiency*					3	2 A	1	5	2007
	Costs					1	5			Int.
Patient-related element	*Patient-related juridical aspects*									
	Ethics									
	Psychological reactions	1	5							Int.

Table 5.3: Summary of the results (2)

Cardiac Surgery

Clinical element

In cardiac surgery a few studies were performed regarding the clinical element; the safety and applicability of the DVSS in cardiac surgery were studied. The highest level of evidence was 4, but the results were promising. No data was received from the semi structured interviews.

Economic element

A relatively high quality study (level of evidence 2B) was reported concerning the hospital costs. A retrospective review of clinical and financial data was performed. The DVSS did not significantly increase hospital costs. No data was received from the semi structured interviews.

Patient-related element

No reports were found regarding patient-related elements in cardiac surgery using the DVSS. During the interviews a respondent mentioned that more attention should be given to ethical issues: *"Within urologic surgery ethics is not a big issue because the risks for the patient are not different from the regular laparoscopic surgery. Other disciplines should have more attention for this variable, for example cardiac surgery."*

Sub conclusion

The DVSS was developed for cardiac surgery, but the diffusion in this area seems to decrease. The DVSS is not assessed for cardiac surgery recently. Most studies date from 2002 to 2005. This decrease of diffusion and studies indicate a slow "death of diffusion" for the DVSS in this specialty, although the results of the costs and the applicability and safety were promising. Possibly a study about the acceptability or the diffusion of the DVSS in this specialty can find an explanation for the decrease of diffusion in cardiac surgery. Unfortunately, the respondents were not experienced with cardiac surgery using the DVSS, therefore there are no data from that source.

General Surgery

Clinical element

In general surgery most research was performed to find new applications of the DVSS. The applicability studies and effectiveness studies are relatively high of quality; the highest level of evidence is 2B. Even in this early stage of diffusion of the DVSS in this specialty, RCT's are performed to study the safety and efficacy. Some results in the clinical element are promising, others are arguable or even negative. For example, in Heller Myotomy the use of the DVSS may reduce perforation rate and improve outcome (Iqbal et al., 2006), while in Roux-en-Y Gastric Bypass there were no clinical advantages (Sanchez, et al., 2005) and in Nissen fundoplication there was no additive value detected up to six months after surgery (Draaisma et al., 2006). Studies regarding the other variables were not found. No data was received from the semi structured interviews.

Economic element

The efficiency and the costs of the DVSS in general surgery were reported in 8 articles. The efficiency was studied within one of the RCT mentioned in the clinical element; in Roux-en-Y Gastric Bypass there were no clinical advantages, but the operating time was significantly shorter (Sanchez, et al., 2005). For end-to-end anastomosis similar results were given, but with a level of evidence of 5. In micro vascular anastomosis the efficiency gave different results; no clear decreased operative time was observed in a case series. A RCT regarding laparoscopic fundoplication revealed that the operative time could be shorter if performed by an experienced team. The results are thus different per surgical technique and contradicting. The costs were studied in two level 4 studies regarding

laparoscopic Nissen fundoplication and laparoscopic rectopexy and an RCT regarding laparoscopic fundoplication. All studies revealed that the overall costs were higher when using the DVSS.
Evaluating the theoretical framework: both the efficiency and the costs are studied in an early stage of diffusion using high quality research designs. No data was received from the semi structured interviews.

Patient-related element
No reports have been found in the patient-related element regarding general surgery and no data was received from the semi structured interviews.

Sub conclusion
The DVSS is in this specialty in an early stage of diffusion. Though, it already has a high rate of high quality research with even a few RCT's (Oxford's level of evidence: 1B). In this early phase of diffusion the applicability, effectiveness, safety, efficacy, efficiency and costs are studied. The economic results are contradicting with a negative character. No research has been performed in the patient-related element.
No data could be received from the semi structured interviews, because the respondents were not experienced in general surgery with the DVSS. Some respondents did mention that projects were starting to implement the DVSS in general surgery.

Gynaecologic Surgery
Clinical element
Gynaecologic robotic-assisted surgery is in an very early phase of diffusion. Four studies have been performed regarding the applicability and effectiveness in the last two years. Especially hysterectomy is a much attentive application with promising results from relatively high quality research (level 2B). No data are received from the semi structured interviews.

Economic element
No reports have been found concerning the economic elements of gynaecologic surgery and no data are received from the semi structured interviews.

Patient-related element
Also no reports have been found regarding the patient-related element and no data are received from the semi structured interviews.

Sub conclusion
The DVSS in gynaecologic surgery is, compared to general surgery, in a very early phase of diffusion; only the clinical elements are studied. The clinical results for use of the DVSS in gynaecologic are promising, but more research with a higher level of evidence is necessary to validate the results. According to a respondent of the interviews the division of gynaecologic surgery of his hospital was starting to use the DVSS.

Paediatric Surgery
Clinical element
As in gynaecologic surgery new applications and effectiveness studies have been performed. Studies regarding the other clinical elements have not been reported. The DVSS has been studied for pyeloplasty paediatric urologic and cardiothoracic surgery. One review described a wide range of applicability, but does not describe the outcomes. The preliminary results of the other studies are

comparable with conventional laparoscopic paediatric surgical techniques. No data have been received from the interviews.

Economic element
No reports have been found concerning the economic elements of paediatric surgery and no data are received from the semi structured interviews.

Patient-related element
No reports have been found concerning the economic elements of paediatric surgery and no data are received from the semi structured interviews.

Sub conclusion
The development and diffusion of robotic-assisted paediatric surgery is similar to gynaecologic surgery; only new applications and effectiveness have been studied. The studies date from 2005 to 2008. The study with the highest level of evidence (level 2B) dates from 2008. The results are promising, but very preliminary.

Thoracic Surgery
Clinical element
For thoracic surgery with the DVSS five applicability studies have been performed. Within these studies the DVSS was applied to thoracoscopic oesophagectomy, thymectomy, resection of mediastinal masses, video-assisted thoracic surgical lobectomy and thoracoscopic surgery for oesophageal tumour treatment. Studies regarding other clinical variables have not been reported. The respondents of the interviews did not have experience with thoracic surgery with the DVSS.

Economic element
No reports regarding the economic elements of thoracic surgery using the DVSS were found and no data was retrieved from the respondents.

Patient-related element
Likewise no data for the patient-related element was retrieved.

Sub conclusion
Only a few applications of the DVSS in thoracic surgery have been reported. It is not clear how the diffusion process of the DVSS in thoracic surgery will develop, because the latest report dates from 2006.

Urologic Surgery
Clinical element
The literature review resulted in reports regarding the applicability, indications, and effectiveness. No reports were found regarding the other clinical variables. Applications the most performed and studied are the partial nephrectomy, pyeloplasty, cyctectomy and radical prostatectomy. Radical prostatectomy is the leading application. In the clinical element most reports were found for the variable 'applicability'. The results for the applicability are relatively positive. Four reports were found studying the effectiveness; all results were arguable. The results regarding the indications are neutral and the results concerning the social outcomes are positive. Urologic surgery is the only specialty with results on the variable 'indications' and 'social outcomes'. The highest level of evidence in the clinical element is 2A.

The results of the interviews revealed that the utilization of the DVSS for urology is increased in the Netherlands, but there was no data available for public. The DVSS has a positive social-environmental impact; patients return earlier to home and work due to shorter hospital stay and less incontinence. Another effect is that a decrease in potencyproblems affects relationships positively. These results have not been confirmed with reports from the literature review. A few respondents mentioned that they were disappointed in the levels of evidence of the studies that were performed. According to the respondents is it not ethical and very time-consuming to perform research with a higher level of evidence, like a RCT.

Economic element
Three reports were found about the efficiency of the DVSS. They all studied the operative time. Using the DVSS did not result in significant shorter operative time in pyeloplasty and prostatectomy. Studies regarding the variable 'costs' were not reported.
The interviews revealed that there are logistic problems (available operative time, planning) with the DVSS. A view projects/studies have been started to analyze the possible savings in disposables and the efficiency of use of the DVSS, but no data available yet. Also the costs are administered and the cost-effectiveness will be studied in one hospital. Likewise, there is no data available yet. The respondents did not know what research methods will be used in the projects.

Patient-related element
No reports have been found concerning the patient-related element in urologic surgery with use of the DVSS. All respondents mentioned that the patients have typical psychological reactions regarding the use of the DVSS; they are attracted to it and specifically ask for robot-assisted surgery. But no research has been performed in this area. According to the respondents this would be interesting for behavioural science.

Sub conclusion
Most research regarding the DVSS is concerning urologic surgery, but the level of evidence in relation to the phase of diffusion is disappointing. General surgery is in an earlier phase of diffusion, but has a higher level of evidence. Though, urologic surgery is the only specialty with results on the variable 'indications' and 'social outcomes'. Possibly, the social outcomes have been studied because of the incontinence and potency problems that occur a lot in radical prostatectomy and can have a high social-environmental impact. Remarkably there are no reports regarding the safety and costs.

5.4 Diffusion of the DVSS

The DVSS has promising results for general, gynaecologic, paediatric and thoracic surgery. Robotic-assisted surgery is in these specialties still in it's infancy, but some results are encouraging. In cardiac surgery the diffusion decreases. The DVSS will probably disappear from that specialty. A descriptive study regarding the acceptability can give insight in the diffusion process.
In urologic surgery, the DVSS has established its place, especially RALP. Though, the DVSS probably will be a success in urologic surgery, more research is necessary to validate the results.

Illustration 5.1 presents the diffusion of the DVSS worldwide regarding the several surgical specialties. The dot at the end of the arrow reflecting the diffusion in cardiac surgery, represents the possible end of diffusion. General surgery is in the early adopters phase. Gynaecologic, paediatric and thoracic surgery are still in the innovators phase and urologic surgery is halfway the early majority in the USA. In the Netherlands the urologic surgery is at the end of the early adopters phase, because most radical prostatectomies are still performed with CLRP or RRP. General, gynaecologic, paediatric and thoracic surgeries are in the Netherlands still in the beginning of the innovator phase; a few projects for applicability have started recently in a few hospitals.

In general, more research is necessary to determine the overall and specific advantages of the DVSS compared to similar treatments. VOI-analysis could be performed to determine more reliable what aspects need to be studied in the future. The DVSS is also an interesting subject for research regarding the diffusion and the variables influencing the diffusion process.

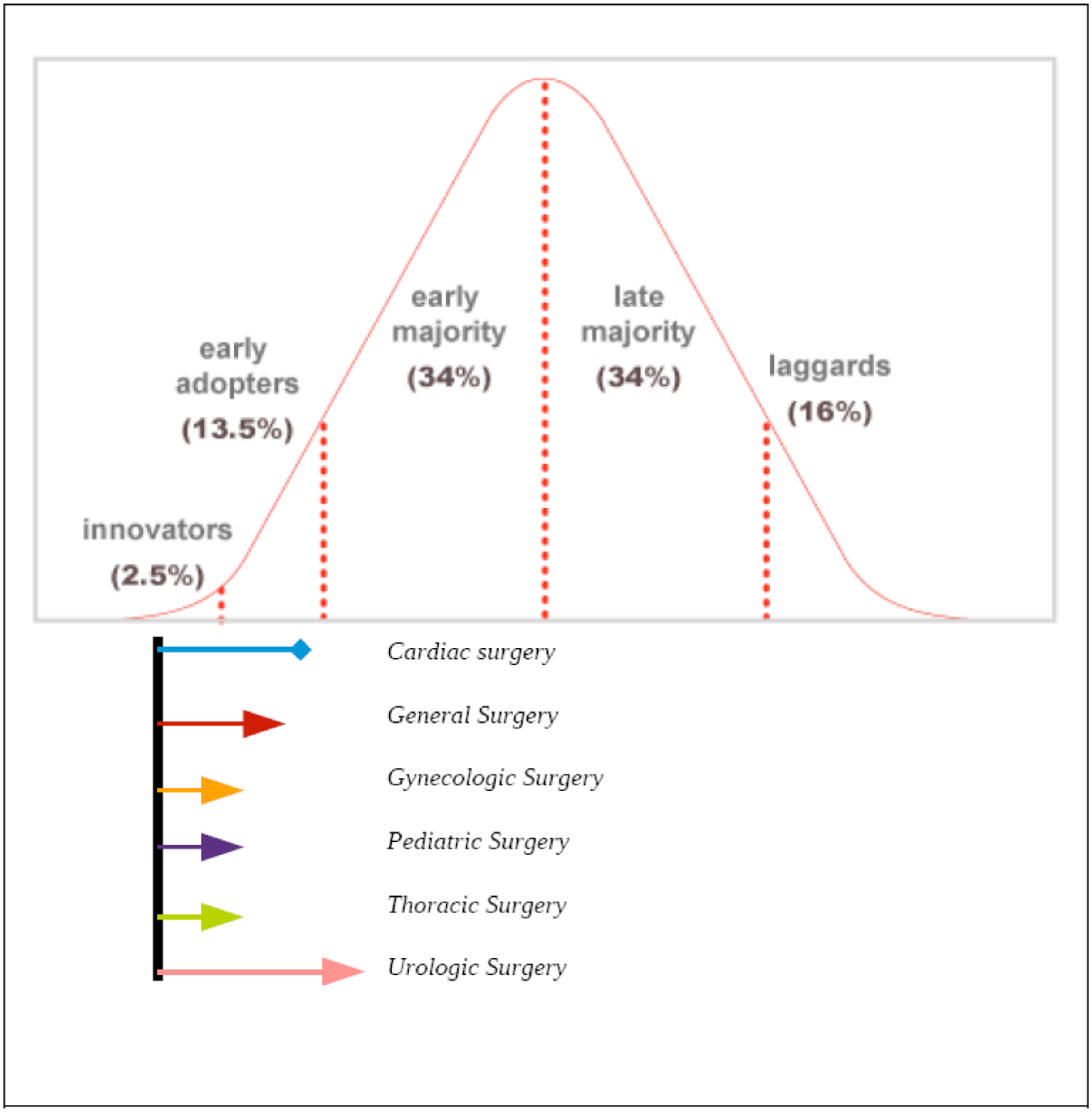

Illustration 5.4: Worldwide diffusion of the DaVinci Surgical System

5.5 *HTA of the DVSS*

With combining the evidence of the articles regarding the impact of the DVSS and the opinions of the respondents of the interviews, insight is given in what aspects are studied and what should be studied. Most research has been performed in the technological, clinical and user element. The results of the interviews confirm this result. The respondents gave feedback on the relevancy of the aspects for the DVSS and surgical innovations in general. After the modifications the list seems complete (see page 45). In the opinion of the respondents, the attributes less important for the DVSS are 'technological complexity', 'observability', 'indications', 'population affected', organisational and patient-related 'juridical aspects', 'characteristics of the organisation, 'accessibility–equity' and 'system-fit'. These elements are perceived as less important because it does not affect the quality of the treatment, according to some respondents. Remarkable is the amount of organisational elements in this list. The respondents were all surgeons, which can cause a bias in this result. Research in the organisational element can give important information for a health care system depending on market forces or crucial information regarding adequate implementation of the surgical innovation.

According to the literature review no surgical specialty gave attention to patient-related elements. A few respondents of the interviews mentioned that ethics should be more considered when performing a new technique or applying the robot in a new surgical specialty.

The research methods that have been used for assessing the DVSS and are being used in general to assess surgical innovations are all based on traditional clinical or economical research designs. Most studies were performed with low quality research designs. But it is possible to use studies with a higher level of evidence in an early phase of diffusion. The studies that general surgery performed are a good example; even in the beginning of the innovator phase relatively high quality research is performed on diverse variables of diverse elements.

A HTA or CTA paradigm or the alternative research methods are not used. The respondents of the interviews were not even aware of these paradigms and alternative methods. They explained that they have to perform the assessments next to the treatments of the patients and are not educated for HTA. It seems welcome to assist the surgeons with performing HTA to enhance the quality of the studies and save time. A prospective study should be performed to evaluate the applicability of the Constructive Health Technology Assessment (CHTA) paradigm and the associated intervention and diagnostic methods in surgical innovations.

6. Conclusion and recommendations

♓

6.1 Introduction

This study started with the development of a theoretical framework for technology assessment of surgical innovations. This theoretical framework is based on theories regarding adoption, diffusion and Health Technology Assessment and consists of a paradigm with a process model and a list of attributes/variables. The theoretical framework can have an important role in the decision-making process for adopting surgical innovations in an early developmental / adoptive phase. It could have an important role in deciding which important aspects to assess and how they need to be assessed. Eventually it could support the evidence based medicine culture, make sure the most effective treatment is chosen for the individual patient in the most efficient manner.

Since the 1970's Health Technology Assessment (HTA) is often used to answer the question whether the new technology should be implemented into clinical practice (Leys, 2003; Berg, Van der Grinten, & Klazinga, 2004). The complexity of the HTA has increased so much that input from other research fields is necessary to maintain its relevance (Battista, 2006). Douma, et al (2007) concluded that Constructive Technology Assessment (CTA) can be used as a complementary approach. CTA takes into account the dynamics of the technology by emphasizing socio-dynamic processes (Douma et al., 2007; Retèl, Hummel, & Van Harten, 2008).

Considering Battista's (2006) and Douma et al's (2007) suggestion, the following research question was formulated:
'What type of Health Technology Assessment (HTA) should be used or how should HTA be adapted to make it applicable for surgical innovations in an early stage of diffusion?'

To be able to answer this research question, five specific questions are formulated. In this concluding chapter first a summary of the answers to the sub-questions is given and then the discussion in relation to the main research question is continued. The five specific questions are:

A. *What paradigm (e.g. Constructive Technology Assessment) can be used to make HTA more applicable for surgical innovations in an early stage of diffusion?*
B. *Which aspects of the adoption / diffusion / implementation of a surgical innovation in an early stage of diffusion are important to assess?*
C. *How are these aspects measurable?*
D. *Which aspects are measured during the diffusion of Robot Surgery, how are these aspects measured and what are the results of these studies?*
E. *Which aspects need to be assessed in future studies during the diffusion of Robot Surgery to enhance complete diffusion and which method can be used?*

6.2 Answers specific research questions

A. ***What paradigm (e.g. Constructive Technology Assessment) can be used to make HTA more applicable for surgical innovations in an early stage of diffusion?***

"HTA is the systematic evaluation of properties, effects, and/or impacts of health care technology" (Goodman & Ahn, 1999). At a more specific level, HTA is an assessment of the preconditions for and the consequences of using health technology. HTA is a systematic, research-based approach, but there is no single method or one delimited research field. Timing of HTA is very important. Technologies may be assessed at different stages of diffusion and maturity. An assessment is the most reliable when the technology is used in routine basis. From an ethical perspective and an economic perspective this cannot be performed, especially for (expensive) surgical innovations with high risks for the patient. To know the full impact of such a complex surgical innovation, you need a broad assessment which is time-consuming when using only traditional research methods. Also the problem of 'ceteris paribus' and/or the 'Collingridge Dilemma' is then created (see page 32). HTA studies that assume the surgical innovation and its environment to be stable, are likely to produce outdated evaluations (Douma et al., 2007). Especially HTA's performed in an early phase of diffusion with a high chance of modification of the surgical innovation. An assessment at that early stage requires structuring the possible scenarios, computing their probabilities and assessing their consequences (Pietzsch & Cornell, 2008). Therefore the focus of HTA studies needs to shift from studying the quality of a new technology to optimizing the technology's quality and effectiveness under dynamic circumstances. Therefore a flexible, iterative and ongoing assessment is necessary. CTA is a paradigm to overcome the problem of 'ceteris paribus' and/or the 'Collingridge Dilemma'. CTA starts already in the design and development phase. Because of the dynamic character of CTA that goes along with the dynamic character of the technology, different approaches are being used. CTA uses different diagnostic methods in different phases of diffusion. Diagnostic methods of CTA include traditional social science techniques and also socio-technical mapping techniques to identify the past and possible future scenarios of technology dynamics (Douma et al., 2007). CTA also provides intervention strategies to influence technological development and application, including awareness initiatives, controlled experimentation, consensus conferences, and dialogue workshops (Douma et al., 2007). Theoretically, CTA combined with HTA, Constructive Health Technology Assessment (CHTA), seems more effective and more applicable for complex surgical innovations then HTA alone. Unfortunately, it was not possible to evaluate the applicability of CHTA. This needs to be studied prospectively.

B. ***Which aspects of the adoption / diffusion / implementation of a surgical innovation in an early stage of diffusion are important to assess?***

Based on the definition of surgical innovation and the theories of diffusion of innovations and HTA/CTA, a list of aspects is developed (see Table 4.4 on page 27-31). It is difficult to determine the most important aspects for surgical innovations due to the broad definition of surgical innovation. A selection of aspects needs to be made depending on the characteristics of the surgical innovation. All attributes should be taken into consideration for the assessment, but in the actual design, only those are included that are estimated relevant for the particular technology and environmental interaction and phase of diffusion. For surgical innovations, the acceptability of the user and the ethical considerations seem to be the most important aspects for the success of the diffusion. This is because the acceptability of the technology by the user and the ethical considerations of using the technology are highly influencing the adoption/diffusion. Other aspects seem also important, because the acceptability seems highly influenced by other aspects (like complexity and effectiveness).

The phase of diffusion also determines which aspects to assess. Some variables require a certain amount of users and/or patients to ensure the quality of the evidence, but it is possible to assess surgical innovations in an early phase of diffusion with use of other than traditional clinical research strategies (e.g. the strategies used in CTA).

Aspects of surgical innovations that are relatively important and possible to assess in an early phase of diffusion are all technical attributes, the applicability, safety and effectiveness, ethical and juridical aspects, risks of malpractice litigation, complexity of usage and acceptability (based on the interviews). Because surgical innovations can have a very experimental character with high (or unknown) risks, the ethical and juridical aspects need special attention in this phase. The ethical and juridical aspects are highly influenced by the (perceived) safety and effectiveness of the innovation, which makes the safety and effectiveness also important aspects in this early phase of diffusion. Likewise, the technical attributes and complexity of usage need to be assessed as early as possible, because it is easier to modify the surgical technology when it is not embedded in routine. The applicability is an aspect that needs to be studied before studying the effectiveness. The risk of malpractice litigation is as important as the safety of the patient; the user needs to be protected too. An indication of the safety of the patient as well as the user can be made in an early stage. Acceptability by the user seems the most important influencing factor for diffusion, especially in an early stage of diffusion where the opinion leaders are driving the diffusion. Diffusion amongst opinion leaders holds the key to product diffusion as a whole (Rogers, 2003). A study to determine/explain the factors influencing the acceptability by the user and the influence on the adoption/diffusion needs to be performed to validate this statement.

C. ***How are these aspects measurable?***

It is possible to measure the attributes discussed in the previous paragraph in an early phase of diffusion and let the results assist in the decision-making. The technological attributes, like reinvention or accuracy, reliability & validity can be measured and adapted in the development phase with use of the intervention strategies of CTA. Accuracy, reliability and validity can be measured in an experimental (animal or technical) study. Performing Strategic Niche Management or Socio-Technical Scenario Drafting can be helpful to determine reinvention possibilities and desires. Experimental studies and case study research can be used to measure applicability. Safety, effectiveness and efficacy can be measured in case series in the early adopter phase. Decision analysis methods and/or value-of-information (VOI) analysis can then help to determine whether additional research is worthwhile, but can also help to determine how research efforts should be prioritized.
According to the respondents of the interviews, such alternative research methods are not used currently to assess surgical innovations; only traditional clinical and economical research designs are used. A prospective study evaluating the experiences with these methods could give insight in the applicability and added value of the alternative diagnostic and intervention methods provided by CTA.

D. ***Which aspects are measured during the diffusion of robot surgery, how are these aspects measured and what are the results of these studies?***

The aspects measured during the diffusion of robot surgery with use of the DVSS are mainly 'risk of malpractice', 'education', 'applicability', 'effectiveness', 'efficiency' and 'costs'. The variables in the organisational element and the patient-related element are the least studied. The aspects are measured with use of traditional clinical and economical research designs. Mainly, the level of evidence is relatively low, except in general surgery. General surgery is a good example that high quality studies are possible to perform in an early phase of diffusion. No paradigm is used to guide the HTA.

The results of the studies regarding the user element (risk of malpractice litigation, education-training, job performance) are relatively positive. No research has been performed in the organisational element, except for the numbers of adoption from the Intuitive Surgical Inc. website. The results of the accuracy study was positive and the results of the reinvention studies were diverse. The clinical and the economic element's results seem to be depending on the surgical technique at hand. It is not possible to give an overall conclusion on the performance of the DVSS.

*E. **Which aspects need to be assessed in future studies during the diffusion of robot surgery to enhance complete diffusion and which method can be used?***

In future studies, the following aspects need more attention: 'environmental preconditions', 'accuracy, reliability and validity', 'reinvention', 'adoption-diffusion-dissemination', 'implementation-assimilation', 'characteristics of the environment, 'characteristics of the organisation', 'indications', 'social outcomes', 'safety', 'efficacy', 'costs', and 'ethics'.

A study of the environmental preconditions can overcome the problems that have occurred during the implementation of the DVSS in some hospitals in the Netherlands. A design of a adequate operative theatre is desirable. The accuracy, reliability and validity need to be studied in general use; the studies that have been performed until now were in an experimental setting and a report of a failure incident. According to the respondents there is a lack of initiatives for reinvention. The DVSS can be adapted and become applicable to even more complex surgical techniques. Reinvention can also enhance the complexity of usage.

The methods that can be used to enhance complete diffusion are a combination of diagnostic methods and intervention methods. Diagnostic methods are used to assess the quality of the innovation. Intervention methods are used to influence technological development and application (Douma et al., 2007). The diagnostic methods include traditional research designs and socio-technical mapping techniques. Intervention methods are action techniques, including awareness initiatives, controlled experimentation, consensus conferences, and dialogue workshops, to influence technological development and application (Douma et al., 2007). Theoretically are technology forcing, socio-technical scenario drafting and strategic niche management no options; these techniques start before development in the design phase. But maybe they can be applied to the future applicabilities of the DVSS and/or the reinvented DVSS. To decide which method to use and how to prioritize the aspects to assess, Value of Information (VOI) techniques can be useful. VOI analysis evaluates the extent to which new evidence might improve expected benefits by reducing the chance for error and compares that improvement with the cost of the information. Thus, VOI is the amount a decision maker would be willing to pay for information prior to making a decision. The applicability of the suggested methods needs to be evaluated in a prospective study.

6.3 Conclusion: HTA for surgical innovations in an early stage of diffusion

HTA for surgical innovations is characterized by a broad spectrum of variables. Surgical innovations can have great consequences on diverse aspects, because performing a surgery is a complex process with clinical and logistic protocols. Also the definition of surgical innovation requires a broad spectrum of variables, because the definition is very general to make it applicable for different kinds of surgical innovations. Therefore a holistic vision is needed. Depending on the technology at hand, the assessment has to focus on a mix of relevant aspects. Based on the results of the interviews and the available research methods for early assessment, the following aspects of surgical innovations should be assessed in an early stage of diffusion: 'environmental preconditions', 'accuracy, reliability & validity', 'reinvention', 'applicability', 'effectiveness', 'social outcomes', 'safety', 'risk of malpractice litigation', 'acceptability of the user' and the 'ethical considerations'. These aspects seem to be possible to assess and relevant in that stage. In/after the early adopterphase, the organisational element gets more important, because the driving forces of adoption and the used implementation strategies can enhance a smooth diffusion. When starting HTA, all aspects should be taken into consideration for the assessment, but in the actual design, only those are included that are estimated relevant for the particular technology, environmental interaction and phase of diffusion. The prioritization of aspects can be determined by using VOI analysis.

Nowadays technologies / innovations are very often modified as they are disseminated. Technologies may be assessed at different stages of diffusion and maturity. This also applies for surgical innovations. This requires a dynamic, iterative and ongoing assessment with use of diagnostic and intervention strategies. CTA combined with HTA (CHTA) seems a possible solution, because CTA starts before the new technology has been introduced into clinical practice, goes on during the phases of diffusion, and is a dynamic way of assessment. CTA includes intervention methods like Technology Forcing, Strategic Niche Management and Socio-Technical Scenario Drafting. These methods can be used in an early stage of diffusion to predict possible future scenarios and probably decrease the problem of uncertainty of information. The methods of HTA can be used for diagnosing. Every assessment strategy has his benefits as well as his doubts. It is important to weigh the pros and cons to choose the best assessment strategy for that specific study. Decision analysis and value-of-information (VOI) analysis should be used to determine whether an innovation should be adopted, whether additional evidence to further inform that decision is worth gathering, and what kind of information is of the greatest value (e.g. which aspects need to be assessed). These techniques cannot only help to determine whether additional research is worthwhile, but can also help to determine how research efforts should be prioritized.

These methods are likely to fit within the paradigm of CHTA in an early stage of diffusion, especially for the early adopter and early majority phase. It can probably help the early adopter to decide which additional research they have to do and it can help the group of early majority to make a decision about the adoption of a new medical technology with less uncertainty. A prospective study is necessary to evaluate the applicability of CHTA and its strategies.

6.4 Recommendations

This master thesis had an explorative character to review the available adequate HTA paradigms, determine aspects important to assess surgical innovations (in an early stage of diffusion) and review the available research strategies adequate for early assessment. The applicability of the HTA paradigms and research strategies need to be evaluated in a prospective study with a technology in the early development phase as subject of the assessment. Then the intervention methods can be evaluated adequately.

The population used for the interviews is small and existed only of surgeons. Other actors in the process of adoption (and development) should be included to determine the relevancy of the individual aspects and completeness of the list. The list of variables and the prioritization of the aspects can probably be validated with use of VOI analyses.

It would be interesting to study the factors that influence the acceptability of the surgical innovation by the user. The results of that study can then be taken into consideration in the development of a surgical innovation. Based on the interviews the factors that influence the diffusion are characteristics of the environment and the acceptability by the user. A study determining/explaining the factors influencing the diffusion of a surgical innovation could give rise to new strategies enhancing a smooth diffusion.

6.5 Discussion

When assessing surgical innovations, more emphasis should be on economical and ethical aspects. Surgeons and other physicians are naturally attracted to new technology. Politicians, patients and physicians all want the (perceived) best treatment, best care and best cure. The newest technology is often perceived as the best treatment, which is generally most expensive and may not be necessary. This continued emphasis on innovation can lead to neglect of the current skills and technology. Some less expensive alternatives may also be sufficient; there is a reason why not everyone drives a Bentley (Buskens, 2008). There is, however, a need for a more careful choice between the most expensive treatment and a sufficient alternative. Here there are two perspectives: individual patient perspective and public (economical) perspective. This is however a difficult and ethical discussion since most people want the best (perceived) treatment for themselves and their loved ones.

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8. Appendices

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Appendix 1.

TOPIC LIST SEMI-STRUCTURED INTERVIEWS

Date:
Place:
Name:
Organisation:

Open questions:

1. When is the DVSS adopted?
2. How went the introduction process?
3. How did you know of the existence of the technology?
   a. Which data has been used to decide to adopt the DVSS?
   b. Who made the decision to adopt?
   c. Have trainings taken place?

4. To which aspects has research been done?
   a. Why these aspects?
   a. Who have been involved in conducting research?
   b. Are these studies started immediately after adoption? If not, when were they performed?

5. How did you choose the research topics? Have you used a paradigm to choose research topics?
6. Do you have knowledge about / have you heard of HTA / CTA?

7. Which research methods have been used?
   a. Do you have knowledge about other research methods then traditional clinical and economical research methods? Which methods do you know?
   b. Do you have knowledge about / have you heard of scenario drafting, technology forcing en/of strategic niche management?

Questions regarding the lists of variables:

1. Is there research performed regarding these aspects?
2. What research methods have been used?
3. Are the results published? (title of article / journal / author)

TOPIC LIST SEMI-GESTRUCTUREERDE INTERVIEWS (Original Dutch version)

Datum:
Plaats:
Naam:
instelling:

Open vragen:

1. Sinds wanneer wordt de DVSS gebruikt?
2. Hoe is het introductieproces verlopen?
    a. Hoe kwam men op de hoogte van de technologie?
    b. Op basis van welke gegevens is de beslissing tot adoptie genomen en door wie? (Heeft er een literatuurstudie plaatsgevonden?)
    c. Hebben er trainingen plaatsgevonden?

3. Naar welke aspecten/onderwerpen is onderzoek gedaan?
    a. Waarom deze aspecten?
    b. Wie zijn betrokken bij het uitvoeren van onderzoek?
    c. Zijn deze onderzoeken gelijk gestart? Zo nee, in welke fase?

4. Is er gebruik gemaakt van een bepaald paradigma bij het kiezen van onderzoeksonderwerpen?
    a. Bent u bekend met HTA / CTA?

5. Welke meetmethodes / onderzoeksmethodes zijn er gebruikt?
    a. Bent u bekend met alternatieve onderzoeksmethoden (zo ja, welke?)
    b. Bent u bekend met scenario drafting, technology forcing en/of strategic niche management?

Vragen aan de hand van lijst met variabelen:

1. Is er onderzoek gedaan naar de volgende aspecten?
2. Welke onderzoeksmethoden zijn gebruikt?
3. Is daar documentatie van? Zo ja, hoe zijn die te verkrijgen?

Appendix 2.

SEARCH TERMS USED IN LITERATURE REVIEW REGARDING CASE STUDY DVSS

Inclusion criteria:
- Articles regarding robotic assisted surgery performed with the DaVinci Surgical System

Exclusion criteria:
- If there is a report with a higher level of evidence regarding the same subject / surgical technique with similar results, the report with the lowest level of evidence will be excluded.

Search terms:

DaVinci Surgical System OR DaVinci robot
Robot-assisted surgery
Endoscopic surgery AND robot
Cardiac surgery
General surgery
Thoracic surgery
Urologic surgery
Gynecologic surgery
Pediatric surgery

Technological elements	Environmental Preconditions OR environment OR operating theatre
	Accuracy, reliability & validity
	Technological complexity OR maintenance
	Reinvention OR adaptation
	Observability
Organisational elements	Adoption OR Diffusion OR Dissemination
	Implementation OR Assimilation AND strategies
	Characteristics of environment OR politics OR strategic management OR demography
	Characteristics of organisation OR size OR organisational structure OR organisational complexity OR (de)centralisation OR innovativeness OR leadership
	Accessibility OR Equity OR access
	System-fit OR technology integration OR compatibility
	Juridical aspects

User elements	Risk of malpractice litigation OR ergonomics OR user safety OR safety surgeon
	Skills
	Education OR Training
	Team performance
	Job performance
	Psychological reactions of the user OR job satisfaction
	Complexity of usage OR Human-System interaction OR user friendliness
	Acceptability OR acceptance
Clinical elements	Applicability OR new applications OR feasibility
	Indications
	Population affected OR epidemiology
	Utilization
	Effectiveness OR DALY
	Social outcomes OR Social-environmental impact OR Quality of life OR QALY
	Safety
	Efficacy OR DALY
Economic elements	Efficiency OR time OR energy OR equipment OR disposables
	Costs OR cost-effectiveness OR Cost-utility OR Cost-benefit
Patient Related elements	Patient-related juridical aspects
	Ethics
	Psychological reactions

Appendix 3.

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
Technological elements	**Environmental Preconditions**	5 2008	Intuitive Surgical Inc. provides information about the environmental preconditions. Though, 3 hospitals located in the Netherlands have had problems with the implementation of the DaVinci Surgical System due to an accelerated adoption and/or lack of a proper implementation plan considering, among other things, the environmental preconditions. The storage of the system, power supply requirements, compatibility with other systems, and the dimensions of the system gave rise to problems (Result semi-structured interviews).	One remarkable citation from interviews with 5 surgeons in the Netherlands: "It is essential to study the environmental preconditions. In the first place this should be done by the company, and an follow-up study done by the innovators and early adopters. Expectations and ideals can differ from reality" (Result semi-structured interviews).
		5 2008	A citation from interviews with 5 surgeons in the Netherlands: "Based on my experience, the robot needs to be integrated in the operation theatre" (Result semi-structured interviews).	Future research question: How should the DaVinci Surgical system idealy be integrated in the operation theatre?
	Accuracy, reliability & validity	5 2008	A case report described the following failure: The articulation joint of an Endowrist needle driver was broken and positioned at such an angle that made it impossible to remove through the trocar (Koliakos, Denayer, Willemsen, Schatteman & Mottrie, 2008).	There are little public reports about failures of the DaVinci Surgical system.
		5 2006	The results of 2 studies regarding the evaluation of technical specifications are: The daVinci surgical system has been shown to have an expected localization error of 1.02 mm, which is comparable to other common localization devices (Kwartowitz, Herrell, & Galloway, 2006). The daVinci-S system has been shown to have an expected localization error of 1.05 mm as compared to the daVinci "classic's" expected error of 1.02mm (Kwartowitz, Herrell, & Galloway, 2007). The difference in localisation error is minor and thus both systems would be appropriate to use in a robotic image guided surgery system (RIGS system).	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
	Technological complexity	5 2008	A citation from interviews with 5 surgeons in the Netherlands: "The DaVinci Surgical system is fairly complex" (Result semi-structured interviews).	Future research question: What consequence has the degree of technological complexity?
	Reinvention	5 2008	A citation from interviews with 5 surgeons in the Netherlands: "The company has received a lot of ideas for reinvention, but they have not developed them (yet) due to a lack of financial resources. Reinvention takes a lot of time because of the complex legislation (of the FDA)" (Result semi-structured interviews).	More research is necessary to conclude if HF has an additional value. Overall research regarding this variable can be done to find reinvention possibilities. Scenario Drafting could be a useful tool.
		5 2008	There are ideas and initiatives to develop the following applications: flexible arm, force feedback and new combinations of imaging techniques (Result semi-structured interviews).	
		4 2008	Peroperative transrectal ultrasonography (PeTRUS) during robot-assisted laparoscopic prostatectomy (RALP) decreased the positive surgical margin rate at the base of the prostate during the initial experience of RALP (Van der Poel, De Blok, Bex, Meinhardt & Horenblas, 2008).	
		3B 2007	34 inexperienced surgeons, 8 laparoscopic surgeons, 10 surgical experts in robotic assistance were assessed on their perception of Haptic Feedback (HF) during robotic surgery. The data support the conclusion that even beginners quickly experience the perception of HF when performing robotic surgery. With more experience, perception of HF and the level of comfort with robotic surgery increases significantly. This perception of HF makes ''real'' HF less important and demonstrates that its importance is overestimated by novices in robotic surgery (Hagen, Meehan, Inan, & Morel, 2008).	
		5 2008	During the interviews with 5 surgeons in the Netherlands 2 surgeons mentioned that they missed force feedback (Result semi-structured interviews).	
	Observability	5 2008	The following citation is characterizing the response of the interviews: "Great improvements can be made in the reliability of research methodology surgeons are using. This can enhance the observability of results" (Result semi-structured interviews).	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
Organisational elements	**Adoption - Diffusion – Dissemination**	4 2008	Intuitive Surgical Inc. keeps the data online: "As of March 31, 2008, there have been 867 unit shipments worldwide - 647 in the United States, 148 in Europe and 72 in the rest of the world" (Intuitive Surgical Inc, 2008a). In the Netherlands there are 6 DaVinci Surgical systems (Intuitive Surgical Inc, 2008b).	This is an interesting variable for future research. 2 surgeons agreed: "A descriptive multicentre study about the driving forces of adoption and the dynamic process of diffusion of the DaVinci Surgical System would be interesting to me" (Result semi-structured interviews).
		5 2008	The adoption decision and process seems to be led by strategic arguments. Citations from interviews with 5 surgeons in the Netherlands: "Domestic competition was a major driving force in the adoption process." "The adoption decision has been based on theoretical potential. Pure intuition." (Result semi-structured interviews).	
		5 2008	The diffusion process of the DaVinci robot is very dynamic. "It is very interesting to see the diffusion process of the DaVinci robot. It was developed for cardiac surgery, then was adopted in the general surgery, and got a boost in urology, which now is stabilized. Gynaecology is the new application. This process is very interesting because of its dynamics." (Citation semi-structured interviews).	
	Implementation – Assimilation	5 2008	3 hospitals located in the Netherlands have had problems with the implementation of the DaVinci Surgical System due to lack of a proper implementation plan and/or an accelerated adoption (Result semi-structured interviews). Citations from interviews with 5 surgeons in the Netherlands: "An acceleration in the process of adoption caused by domestic competition resulted in implementation problems such as no available storage room, problems with the compatibility with other systems, and shortage of operating time." (Result semi-structured interviews). "Only the financial elements were included in the business plan." (Result semi-structured interviews). "Before adoption a clear implementation plan needs to be written. This should be continuously evaluated." (Result semi-structured interviews).	Citations from interviews with 5 surgeons in the Netherlands: "A retrospective study considering the implementation of the DaVinci robot could give insight in the causes of the implementation problems. ... Maybe in the future such problems can be avoided." "New adopters are not obtaining any information of current users. I would like to share my experience." (Result semi-structured interviews)
	Characteristics of environment	5 2008	Domestic competition drove 2 hospitals to accelerated adoption. A citation from interviews with 5 surgeons in the Netherlands: "Environmental characteristics and strategic arguments caused an accelerated adoption."(Result semi-structured	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
			interviews).	
	Characteristics of organisation			
	Accessibility – Equity	5 2008	In 1 of 5 hospitals that was interviewed there is a waiting list for robot-assisted surgery: "Due to logistic problems there is a waiting list." (Result semi-structured interviews).	
	System-fit / technology integration / compatibility	5 2008	A citation from interviews with 5 surgeons in the Netherlands: "The robot is adopted because it fits the specialties of this hospital: oncology and minimal invasive surgery." (Result semi-structured interviews).	
	Juridical aspects	5 2008	Juridical aspects should be encountered for during the adoption process. The robot is bought with American terms. The American legislation is different from the legislation in the Netherlands. This can cause problems. For example, the sterilisation procedure is different and does not qualify the Dutch terms (Result semi-structured interviews).	There is no research performed yet regarding the sterilisation procedure.
User elements	**Risk of malpractice litigation**	5 2008	4 surgeons mentioned that they experienced the DaVinci Surgical System as more comfortable than a regular laparoscopic surgery due to the surgeon console. A citation from interviews with 5 surgeons in the Netherlands: "It is easy to imagine that working in the surgeon console is more comfortable than standing beside the patient. ... And I can feel it too; on the end of the day I am less tired. ... Research regarding the ergonomics of the surgeon console has no additional value because the result will be so obvious." (Result semi-structured interviews).	
		3B 2007	1 surgeon, 4 laparoscopic and 4 robot assisted Roux-en-Y gastric bypass procedures (RYGBP). These pilot data suggest that robotic RYGBP surgery results in less musculoskeletal stress to the upper back and possibly the upper extremities than standard laparoscopic technique (Lawson, Curet, Sanchez, Schuster, & Berguer, 2007).	
		4	The use of a robot-assisted surgical system was of value in both cognitive and	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
		2008	physical stress reduction. Robotic assistance also demonstrated improvement in performance (Van der Schatte Ollivier, Van 't Hullenaar, Ruurda, & Boerders, 2008).	
	Skills	5 2008	1 surgeon said: "After the innovators phase it should be clear what skills are necessary before individuals start using this new technology" (Result semi-structured interviews).	
	Education – Training	5 2008	A few remarkable citations from interviews with 5 surgeons in the Netherlands: (Result semi-structured interviews): "There are no demands for certification and training. You can 'drive without a license'." "Training were in the early worldwide diffusion better then they are now".	Demands for certification and training can ensure the quality of robotic-assisted surgery. Therefore, demands and criteria should be developed.
		4 2006	Development and evaluation of a clinic-like training program with a pre-test and a post-test for the clinical introduction of the DaVinci robotic system in visceral and vascular surgery. 4 trainees with different surgical levels of experience participated. The operative times, the number of complications, and the performance quality were measured. The presented experimental small and large animal model is a standardized and reproducible training method for robotic surgery that allows evaluation of the surgical performance while shortening and optimizing the learning-curve (Mehrabi et al., 2006).	
		2B 2007	Duration and accuracy were measured in inexperienced participants performing 176 randomized laparoscopic tasks. Robotic assistance resulted in faster and more accurate performance. Conventional laparoscopy resulted in faster skill acquisition (Heemskerk, Van Gemert, De vries, Greve, & Bouvy, 2007).	
		4 2004	13 surgeons completed 5 synthetic small bowel anastomosis. A rapid learning curve to a competent level is possible aided by the system's intuitive motion. Motion analysis is a useful tool to measure performance in the da Vinci system compared to qualitative analysis (OSATS) and time analysis alone (Hernandez et al., 2004).	
		4 2006	7 right-handed medical students were trained in 3 tasks with the DaVinci Surgical System over 4 weeks. These subjects, along with 8 control subjects, were tested before and after training. Electromyographic (EMG) signals were collected from	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
			arm and hand muscles during the testing sessions. The results suggest that training reduces muscle fatigue as a result of faster and more deliberate movements. These changes occurred predominantly in muscles that were the dominant muscles for each task, whereas the more demanding task recruited more diverse motor units. An evaluation of the physiologic demands of robotic laparoscopic surgery using EMG is a meaningful quantitative way to examine performance and skill acquisition (Judkins, Oleynikov, Narazaki, & Stergiou, 2006).	
	Team performance	5 2008	In all hospitals in the Netherlands the operating time is administrated. 3 surgeons mentioned that the operating time decreases when the team is getting more experienced with the DaVinci surgical system and each other (Result semi-structured interviews). A citation from interviews with 5 surgeons in the Netherlands: “When working with a fixed specialized team, routine results in a higher efficiency.” (Result semi-structured interviews)	Future research question: What is the influence of teamplay on team performance?
		5 2008	From the interviews can be concluded that teamplay is an important factor in working with the DaVinci Surgical System. A citation from interviews with 5 surgeons in the Netherlands: “It is important that the team has confidence in each other and needs to be enthusiastic about working with the robot. ... It is important that the team will be educated as a team, not as individuals.” (Result semi-structured interviews)	
	Job performance	5 2008	A citation from interviews with 5 surgeons in the Netherlands: “This is a dangerous variable. ... It is being avoided in the field of research because it gives information about the performance level of individuals. The consequences of this information are frightening.”	Future research question: How would the typical surgeon perform with the DaVinci Surgical System?
		5 2004	The robot system was tested in 10 pigs for aortic replacement, 10 other pigs were operated with standard videoscopic instruments. The operating time was shorter, blood loss was less and job performance was better using the robotsystem (Ruurda, Wisselink, Cuesta, Verhagen & Broeders, 2004).	
		5 2004	Experienced endoscopic surgeons performed end-to-end anastomosis on post-mortem porcine small intestine. Anastomosis time, number of stitches, and the number of knots did not differ significantly between the two groups. The time	

All Surgical Specialties				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks and future research questions**
			needed per stitch was significantly shorter with robot assistance (81.4 sec/stitch vs. 95.9 sec/stitch, p = 0.005). More suture ruptures occurred in the robot group (0 (0–2) vs. 0 (0–0), p = 0.003). In the standard group more stitch errors were found (2 (0–5) vs. 0 (0–3), p = 0.017). These results were comparable for 3 different working directions. The action analysis showed significant benefits of robotic assistance. The benefits were greatest in a vertical bowel position. Robot assistance might offer added value to experienced endoscopic surgeons in the performance of a small-bowel anastomosis, even though total anastomosis time could not be demonstrated to be shorter and some suture tears occurred due to the lack of force feedback (Ruurda, Broeders, Pulles, Kappelhof, & Werken, 2004).	
	Psychological reactions of the user	5 2008	This variable needs to be taken into consideration for further research, because of the following remarkable citations from interviews with 5 surgeons in the Netherlands: “Due to working in the surgeon console, distanced from the team and patient, the work has become lonelier.” “This could be a technology that is adopted for economic reasons. When a surgeon is being pushed to use the robot, or needs to accomplish goals of production, then it could be that some surgeons would not be satisfied with their job anymore” (Result semi-structured interviews).	Future research questions: - What are the psychological reactions of the surgeon and the team after implementing the DaVinci Surgical System? - Do the driving forces of the adoption of the DaVinci Surgical System influence the job satisfaction of the users?
	Complexity of usage - Human-System interaction	5 2008	During the interviews with 5 surgeons in the Netherlands all surgeons declared that the robot is user-friendly (Result semi-structured interviews).	This should be an important variable during development, with an evaluation in the innovators and early adopters phase.
		5 2008	During the interviews with 5 surgeons in the Netherlands 2 surgeons mentioned that they missed force feedback (Result semi-structured interviews).	
	Acceptability	5 2008	During the interviews 1 surgeon mentioned the following: “The robot almost failed on this variable: the robot was not sufficient accepted in the cardiac surgery, whereas it was specifically designed for cardiac surgery. Urology made that the robot had a comeback.” (Result semi-structured interviews)	

Cardiac Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	5 2004	In 10 female pigs, the infrarenal aorta was partially replaced by a 10 mm polytetrafluoroethylene (PTFE) interposition graft through a videoscopic retroperitoneal approach, using the da Vinci robot system (robot group). 10 other pigs were operated on in a similar fashion, using standard videoscopic instruments (control group). The time was shorter, blood loss was less and job performance was better using the robotsystem (Ruurda, Broeders, et al., 2004).	More research is necessary to indicate the applicability of using the DaVinci Surgical System in replacing the infrarenal aorta partially.
		4 2007	Data were retrospectively collected on 201 patients undergoing a lateral "ports only" endoscopic robotic mitral valve repair at three institutions. Techniques of aortic occlusion included the endoaortic balloon or a transthoracic clamp. The efficacy of the repair was measured intraoperatively by transesophageal echocardiogram. CONCLUSIONS: A lateral endoscopic robotic approach to mitral valve repair is feasible, seems safe, and can be performed consistently with acceptable postoperative results. Further follow-up is required to determine the long-term efficacy of this approach to robotic mitral valve repair (Murphy, et al., 2007).	There has also been a study to indicate the safety of using the DaVinci Surgical System in mitral valve repair. See variable safety on page 80.
		5 2008	In the pig, epicardial 13 MHz ultrasound (introduced through a port and manipulated by the 'da Vinci' system) was able to visualize correctly and incorrectly constructed coronary anastomoses in closed-chest beating heart CABG. During off-line assessment all anastomoses were accurately identified as correct or incorrect by two blinded observers. It therefore is a promising technology for intra-operative anastomotic quality control in totally endoscopic coronary artery bypass surgery (Budde, et al., 2004).	More research is necessary to indicate the applicability of using the DaVinci Surgical System in assessment of constructed coronary anastomoses.
	Indications			
	Population affected			Epidemiological information is available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization			

Cardiac Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
	Effectiveness			
	Social Outcomes			
	Safety	4 2005	In a prospective phase II Food and Drug Administration trial, the safety of performing robotic mitral valve repairs by using the da Vinci surgical system was studied. The mitral valve repairs were performed in 112 patients at 10 centers. Multiple surgical teams performed robotic mitral valve repairs safely early in development of this procedure, with a reoperation rate of 5.4% (Nifong, et al., 2005).	The results need to be compared with a control group in future research.
		4 2006	12 centres have studied the single-vessel LAD revascularization using the DaVinci Surgical System. In 85 patients (69 men, age 58 +/- 10 years) who underwent TECAB, CPB time was 117 +/- 44 minutes, cross-clamp time was 71 +/- 26 minutes, and hospital length of stay was 5.1 +/- 3.4 days. There were five (6%) conversions to open techniques. There were no deaths or strokes, one early reintervention, and one myocardial infarction (1.5%). Three-month angiography was performed in 76 patients, revealing significant anastomotic stenoses (> 50%) or occlusions in 6 patients. Overall freedom from reintervention or angiographic failure was 91%. Robotic TECAB was accomplished with no mortality, low morbidity, and angiographic patency and reintervention rates comparable with published data. Although the use of CPB was a limitation of the technique, this experience represents a step toward more advanced procedures, such as multivessel or off-pump TECAB (Argenziano et al., 2006).	More research is necessary to assess the safety of using the DaVinci Surgical System in TECAB.
	Efficacy			
Economic elements	**Efficiency**			
	Costs	2B 2005	The authors conducted a retrospective review of clinical and financial data of 20 patients who underwent atrial septal defect (ASD) closure and 20 patients who underwent mitral valve repair (MVr) using either robotic techniques or a conventional approach with a sternotomy. Total hospital cost (actual resource consumption) was subdivided into operative and postoperative costs.	

Cardiac Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			RESULTS: Robotic technology did not significantly increase hospital cost. While the absolute cost for robotic surgery was higher than conventional techniques after taking into account the institutional cost of the robot, the major driver of cost for robotic procedures will likely continue to decrease, as the surgical team becomes increasingly familiar with robotic technology. Furthermore, other benefits, such as improvement in postoperative quality of life and more expeditious return to work may make a robotic approach cost-effective. Thus, it is possible that the benefits of robotic surgery may justify investment in this technology (Morgan et al., 2005).	
Patient Related elements	**Patient-related juridical aspects**			
	Ethics	5 2008	Within the cardiac surgery a study about ethics would be relevant, because risks for the patient are higher. A citation from interviews with 5 surgeons in the Netherlands: “Within the urologic surgery ethics is not a big issue because the risks for the patient are not different from the regular laparoscopic surgery. Other disciplines should have more attention for this variable, for example cardiac chirurgy.” (Result semi-structured interviews)	What are patient related ethical issues within different surgical specialities?
	Psychological reactions			

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	3B 2007	Robotic-assisted adrenalectomy is an alternative to laparoscopic adrenalectomy. 3 patients underwent robot-assisted left adrenalectomy in 3 cases of Pheochromocytoma affecting the left adrenal gland. RESULTS: Conversions were none. There was no mortality and post-operative course was uneventful for all the 3 patients. CONCLUSIONS: Robotic adrenalectomy is a feasible alternative to laparoscopic adrenalectomy also for a challenging adrenal disease such as pheochromocytoma (Constanzi, et al., 2007).	
		3B 2001	3 surgeons were trained to perform laparoscopic cholecystectomies with the Da Vinci system. Technical feasibility of robot-assisted surgery was evaluated in 30 laparoscopic cholecystectomies. Set-up time, operating time, complications and technical problems were recorded. In 1 case the cholecystectomy was completed with open surgery. The time needed to install the robotic system decreased with experience of the operating team. Operating time was comparable in robot-assisted cases to the time needed for laparoscopic cholecystectomy in the same clinic. There were no robotrelated complications. Technical feasibility of robot assisted laparoscopic cholecystectomy was demonstrated. The system showed to enhance the surgeon’s dexterity and visualisation possibilities, providing intuitive control of the instruments (Ruurda, Broeders, Simmermacher, Rinkes, & Van Vroonhoven, 2001).	
		2B 2005	This study aimed to analyze the applicability of robotic-assisted laparoscopic gastric bypass. The patients in the robot group were 7 men and 10 women with a mean age of 44 years. Laparoscopic gastric bypass were 139 patients. Follow-up assessment, performed at months 1, 3, 6, and 12, then yearly thereafter, included evaluation of the variations in BMI and the percentage of excess body weight loss (EBWL%). The analysis of follow-up assessment at months 1, 3, 6, and 12 showed a progressive decrease in BMI and an increment of EBWL%. CONCLUSIONS: Early experience suggests that robotic surgery is applicable / feasible and seems an effective alternative to conventional laparoscopic surgery. Global morbidity and the mortality are clearly less than with open gastric bypass. Like laparoscopy, it avoids the big incision, reduces pain, allows early mobilization, and diminishes general (respiratory and circulatory) and local complications (wound infection and incisional hernia) (Parini, et al., 2006). No	Another study assessed the clinical and economic advantages of robotic-assisted laparoscopic gastric bypass compared to laparoscopic gastric bypass.

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			clear advantages compared to laparoscopic were observed, but it could allow complex procedures to be performed with greater precision and better results.	
		4 2005	Nerve-sparing axillary dissection in 4 patients with invasive ductal carcinoma of the breast undergoing segmental (conservative) excision and level II axillary dissection. The time for the robotic axillary dissection ranged from 30 to 105 minutes (average 70.5 minutes). The average number of lymph nodes retrieved was 13 (11, 11, 13, and 17, respectively). Postoperatively all four patients recovered well and were discharged the next day. This procedure with the da Vinci Surgical System is feasible and can be performed within the current oncologic standards (Lim, Kun, & Lam, 2005).	
		5 2003	Robot-assisted laparoscopic choledo-chojejunostomy has been proven feasible in an experimental model on pigs. The procedure can be performed with acceptable time loss (Ruurda, Van Dongen, Dries, Borel Rinkes, & Boreders, 2003).	
		5 2003	20 intestinal anastomosis performed with robotic system, 10 laparotomy. OR time, anastomosis time, and complications were recorded. Effectiveness is recorded by postoperative observation and mechanical integrity. Technical feasibility of performing a safe and efficient robot-assisted laparoscopic intestinal anastomosis in a pig model was repeatedly demonstrated with a reasonable time required for the anastomosis (Ruurda & Broeders, 2003).	
		5 2003	Robot-assisted thoracoscopic extirpation of a thoracic neurogenic tumor is feasible. A 46-year-old woman presented with a history of paravertebral pain. A chest x-ray revealed a left paravertebral mass. A magnetic resonance imaging scan revealed a well-encapsulated mass that was suspected to be a neuroma at the level of T8–T9, separate from vascular structures, without extension in the foramina, and without a spinal canal component. Robot-assisted surgery may prove to be of additional value in challenging thoracoscopic surgery, such as the delicate removal of benign neurogenic tumours, because of the support in manipulation and visualization during videoscopic interventions (Ruurda, Hanlo, Hennipman, & Broeders, 2002).	
	Indications			
	Population			Epidemiological information is

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
	affected			available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization			
	Effectiveness	4 2006	70 patients underwent laparoscopic Heller myotomy. The number of intra-operative perforations and the symptom-predictive value of postoperative esophagogram width measurement at the gastroesophageal junction were analyzed. The overall complication rate was 11%. Four patients experienced intraoperative perforation during the laparoscopic technique. No perforations were experienced with the daVinci robotic system (n = 19). Of the total, 82% of patients had resolution of dysphagia, 91% of regurgitation, 91% of heartburn and 82% of chest pain. Immediate postoperative esophagogram gastroesophageal junction width demonstrated a positive predictive trend from 0 to 10 mm for dysphagia. The use of the daVinci robotic system may reduce the perforation rate and improve outcome, but operative numbers were insufficient to prove these findings statistically (Iqbal, et al., 2006).	
		2B 2005	20 patients with gastro-esophageal reflux disease (GERD) were randomized into laparoscopic Nissen versus robot-assisted Nissen Fundoplication. No clear advantage of using robotics in the Nissen Fundoplication procedure was observed. The procedure seems to be feasible and safe. The technique is limited because of unadapted instruments. The disadvantages are the high costs and prolonged operative time (El Nakadi, et al., 2006).	
	Social Outcomes			
	Safety	1B 2005	The new laparoscopic fellow's first 50 patients were randomized to undergo either laparoscopic Roux-en-Y gastric bypass (LRYGB) or totally robotic laparoscopic Roux-en-Y gastric bypass (TRRYGB). Data were collected on patient age, gender, body mass index (BMI), co-morbidities, operative time, complication rates, and length of stay. Student's t test with unequal variances was used for statistical analysis.	

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			RESULTS: No significant differences in age, gender, comorbidities, complication rates, or length of stay were found between the two groups. CONCLUSIONS: the data indicate that the use of the daVinci Surgical System for TRRYGB is safe, but no differences in complication rates were found between the 2 groups (Sanchez, Mohr, Morton, Safadi, Alami, & Curet, 2005).	
	Efficacy	1B 2006	An RCT was performed to compare standard laparoscopic Nissen Fundoplication (LNF) with robot-assisted Nissen Fundoplication (RNF). RNF yielded similar subjective and objective results to LNF in this study. Therefore no additive value of robotic systems for this procedure was detected up to 6 months after surgery (Draaisma, et al., 2006).	
Economic elements	**Efficiency**	5 2006	Microvascular anastomosis in breast reconstruction. The time to perform this anastomosis was about 40 min and significantly longer than the standard technique (around 15 min). The theoretical advantages of performing robotic surgery, minimalization of tremor and scaling of movement, were not yet translated into a clear advantage e.g. decreased operating time (Van der Hulst, Sawor, & Bouvy, 2006).	
		5 2004	Experienced endoscopic surgeons performed end-to-end anastomosis on post-mortem porcine small intestine. RESULTS: Anastomosis time, number of stitches, and the number of knots did not differ significantly between the two groups. The time needed per stitch was significantly shorter with robot assistance (81.4 sec/stitch vs. 95.9 sec/stitch, p = 0.005). More suture ruptures occurred in the robot group (0 (0–2) vs. 0 (0–0), p = 0.003). In the standard group more stitch errors were found (2 (0–5) vs. 0 (0–3), p = 0.017). These results were comparable for 3 different working directions. The action analysis showed significant benefits of robotic assistance. The benefits were greatest in a vertical bowel position (Ruurda, Broeders, Pulles, Kappelhof, & Van der Werken, 2004).	
		1B 2005	The new laparoscopic fellow's first 50 patients were randomized to undergo either laparoscopic Roux-en-Y gastric bypass (LRYGB) or totally robotic laparoscopic Roux-en-Y gastric bypass (TRRYGB). Data were collected on patient age, gender, BMI, co-morbidities, operative time, complication rates, and length of stay. Student's t test with unequal variances was used for statistical analysis.	

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			RESULTS: No significant differences in age, gender, co morbidities, complication rates, or length of stay were found between the two groups. The mean operating time was significantly shorter for TRRYGB than for LRYGB (130.8 versus 149.4 minutes; P = 0.02), with a significant difference in minutes per BMI (2.94 versus 3.47 min/BMI; P = 0.02). The largest difference was in patients with a BMI >43 kg/m(2), for whom the difference in procedure time was 29.6 minutes (123.5 minutes for TRRYGB versus 153.2 minutes for LRYGB; P = 0.009) and a significant difference in minutes per BMI (2.49 versus 3.24 min/BMI; P = 0.009). CONCLUSIONS: The operating room time is shorter with the use of the robotic system during a surgeon's learning curve, and that decrease is maximized in patients with a larger BMI (Sanchez et al., 2005).	
		1B 2007	40 patients with gastro-oesophageal reflux disease were randomized to either robotic-assisted laparoscopic Fundoplication (RALF) by use of the DaVinci Surgical System or conventional laparoscopic Fundoplication (CLF). Nissen Fundoplication was the standard anti-reflux procedure. Peri-operative data such as length of operative procedure, intra- and postoperative complications, length of hospital stay, overall costs and symptomatic short-term outcome were compared. The total operative time was shorter for RALF compared to CLF (88 vs. 102 min; p = 0.033) consisting of a longer set-up (23 vs. 20 min; p = 0.050) but a shorter effective operative time (65 vs. 82 min; p = 0.006). There were no conversions to an open approach. Mean length of hospital stay (2.8 vs. 3.3 days; p = 0.086) and symptomatic outcome 30 days postoperatively (10% vs. 15% with ongoing PPI therapy; p = 1.0 and 25% vs. 20% with persisting mild dysphagia; p = 1.0) was similar in both groups. In comparison with CLF operative time can be shorter for RALF if performed by an experienced team. However, costs are higher and short-term outcome is similar. Thus, RALF can not be favoured over CLF regarding perioperative outcome (Muller-Stich, et al., 2007).	
		4 2007	Robot-assisted laparoscopic Nissen Fundoplication did not result in more complications than conservative laparoscopic Nissen Fundoplication, but no proven benefit. However, the use of robotic assistance took an extra-47 minutes to complete the operation and costs were raised with an accessory 987.47 euro (Heemsker, Van Gemert, Greve, & Bouvy, 2007).	

General Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
		4 2007	Robot-assisted laparoscopic rectopexy results in increased time and higher costs than conventional laparoscopy (Heemskerk, De Hoog, Van Gemert, Baeten, Greve, & Bouvy, 2007).	
	Costs	4 2007	Robot-assisted laparoscopic Nissen Fundoplication did not result in more complications than conservative laparoscopic Nissen Fundoplication, but no proven benefit. However, the use of robotic assistance took an extra-47 minutes to complete the operation and costs were raised with an accessory 987.47 euro (Muller-Stich et al, 2007).	
		4 2007	Robot-assisted laparoscopic rectopexy results in increased time and higher costs than conventional laparoscopy (Heemskerk et al., 2007).	
		1B 2007	40 patients with gastro-esophageal reflux disease were randomized to either robotic-assisted laparoscopic Fundoplication (RALF) by use of the DaVinci Surgical System or conventional laparoscopic Fundoplication (CLF). Nissen Fundoplication was the standard anti-reflux procedure. Peri-operative data such as length of operative procedure, intra- and postoperative complications, length of hospital stay, overall costs and symptomatic short-term outcome were compared. Costs were higher for RALF than for CLF (e 3244 vs. e 2743, p = 0.003) and short-term outcome is similar. Thus, RALF can not be favoured over CLF regarding perioperative outcome (Muller-Stich et al., 2007).	
Patient Related elements	**Patient-related juridical aspects**			
	Ethics			
	Psychological reactions			

Gynaecologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	3A 2007	Several reports have been published since 2005 that describe robotic-assisted simple hysterectomy in terms of technique and experiences (Advincula & Reynolds, 2005; Beste & Nelson, 2005; Fiorentino, Zepeda, & Goldstein, 2006; Reynolds & Advincula, 2006). These reports demonstrate feasability, but are limited in numbers and their results will need to be validated with larger studies (Boggess, 2007).	
	Indications			
	Population affected			Epidemiological information is available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization			
	Effectiveness	2B 2008	Comparison of gynaecologic practice and peri-operative outcomes of patients undergoing total laparoscopic hysterectomy and robotic hysterectomy before and after implementation of a robotics program. A higher likelihood of exploratory laparotomy for hysterectomy in the pre-robotic cohort versus the robotic cohort and a higher likelihood of intra-operative conversion to laparotomy with the pre-robotic cohort than with the robotic cohort existed. Reduced operative time, reduced blood loss, and shortened length of stay may be achieved in patients who are treated robotically versus a non-robotic approach. Robotics may facilitate the minimally invasive treatment of patients while potentially reducing the rate of abdominal hysterectomies (Payne & Dauterive, 2008).	
		2B 2007	Comparison of the surgical and pathologic outcomes of 13 consecutive robotic-assisted Type III radical hysterectomies with 48 historic abdominal radical hysterectomies. All of the robotic procedures were completed successfully without any conversion to laparotomy. There were significantly more lymph nodes recovered robotically than abdominally (33 vs. 22; P = 0.001), no increase in operative time (median 242 vs. 240 min), less blood loss (100 vs. 400 cc), and no	

Gynaecologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			blood transfusions administered to the robotic-assisted surgery patients compared with blood transfusions to 8% of the abdominal controls. Furthermore, all of the robotic-treated patients were discharged within 24 h, and none required intra-venous pain medication compared with an average of three hospital days for the abdominal group (Boggess, 2007).	
		2B 2007	Comparison of 43 robotic-assisted <u>endometrial staging</u> with 101 patients staged laparoscopically. None of the robotic patients were converted to laparotomy versus 3% for the laparocopy group; in addition, significantly more nodes were retrieved (30 vs. 23, p=0.004), less bloodloss (63 vs. 142 cc., p=0.0001); a shorter operative time was required (163 vs. 213 min; p=0.0002), and a shorter hospitalization period was necessary (1 vs. 1.2 days; p = 0.04) with the robotic cohort than with the laparoscopy cohort. The surgeons were able to perform comprehensive staging on larger women (BMI 33 vs. 29; p = 0.008). These data suggest that robotic assistance improves upon the already established laparoscopic approach to the treatment of endometrial cancer (Boggess, 2007).	
	Social Outcomes			
	Safety			
	Efficacy			
Economic elements	**Efficiency**			
	Costs			
Patient Related elements	**Patient-related juridical aspects**			
	Ethics			
	Psychological reactions			

Paediatric Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	5 2006	The robot system is applied in: orchidoplexy, pyeloplasty, uretero-pelvic junction obstruction, ureteral reimplantation, nephrectomy, appendicovesicostomy and bladder augmentation, pyelolithotomy, adrenalectomy, bladder neck sling, pyeloureterostomy, and excision of Mullerian duct remnants. In all cases, the procedure could be completed with surgical success. In these cases, it is difficult to accurately assess the impact on reduction of morbidity, but in all, the enhanced visualization and dexterity was noticeable, even compared with open surgery (Passeroti & Peters, 2006).	It is not clear how many patients were involved and what the outcomes were. This report is a description of all these applications in paediatric surgery.
		4 2005	A retrospective study to evaluate the applicability and outcomes of robotic assisted laparoscopic pyeloplasty in the paediatric population. 7 patients 6 to 15 years old underwent robotic assisted laparoscopic pyeloplasty. All patients underwent dismembered pyeloplasty (Anderson-Hynes). Mean followup was 10.9 months (range 2 to 18). Mean length of stay was 1.2 days (range 1 to 3). Mean operative time was 184 minutes (range 165 to 204), with a mean robotic anastomosis time of 39.5 minutes (30 to 46). Mean estimated blood loss was 31.4 ml (range 10 to 50). 6 of the 7 patients have had followup studies demonstrating improved drainage, symptom resolution and no evidence of obstruction on diuretic renal scans or excretory urogram. Robotic assisted pyeloplasty is feasible in the paediatric population. The precision in dissection, incision and suturing allows for comparable results to open pyeloplasty in this age group (Atug & Woods, 2005).	
	Indications			
	Population affected			Epidemiological information is available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization			
	Effectiveness	2A 2008	The review aims to compare open pyeloplasty with laparoscopic and robotic pyeloplasty in children. 8 studies were included in the review. Open pyeloplasty achieves good results; success rate 90–100%. Laparoscopic pyeloplasty results	

Paediatric Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			are as good as those of open surgery. However, the goal of laparoscopic pyeloplasty as a means of providing minimally invasive surgery to a larger number of patients has not been achieved. The reason for this is the difficulty faced by most urologists in acquiring the technical skills to perform a laparoscopic pyeloplasty. In reports of robot-assisted pyeloplasty, results in the range of 88–97% appear to be achieved. Robotic technology has the potential to make minimally invasive pyeloplasty an easier skill to acquire for a larger number of urologists. Long-term data are required to determine its efficacy (Patel, Patil, Coughlin, Dangle, & Palmer, 2008).	
		3A 2008	This review describes the robotic pyeloplasties and Fundoplications. 31 studies were identified describing 566 patients. 11 studies were in the general paediatric category (274 cases). 1 study described both general and urologic procedures. 13 studies described paediatric urology operations (204 cases) and 6 studies were in the paediatric cardiothoracic category (88 cases). Designs: 4 case control studies, 1 prospective trial / cohort study, case reports or case series. Robotic systems: Da Vinci (23 studies), Zeus (4 studies), AESOP (1 study), unknown (3 studies). CONCLUSIONS: Initial results are encouraging, with a decrease in operating time correlated with an increase in experience. Almost all surgeries have been performed successfully with a small percentage of conversions and complications. Robotic surgery enables more refined hand-eye coordination, superior suturing skills, better dexterity, and precise dissection compared to laparoscopic or open surgeries. The initial cost is an important issue affecting widespread use. The ultimate acceptance of this technology will depend on issues such as size, efficacy, and safety. A well-structured robotics programme could be of great help in making this system a success in paediatric surgery (Sinha & Haddad, 2008).	
	Social Outcomes			
	Safety			
	Efficacy			

Paediatric Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Economic elements	**Efficiency**			
	Costs			
Patient Related elements	**Patient-related juridical aspects**			
	Ethics			
	Psychological reactions			

Thoracic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	4 2006	The Applicability of robot-assisted thoracoscopic esophagectomy (RTE) with mediastinal lymphadenectomy was assessed prospectively. 21 consecutive patients with esophageal cancer underwent RTE. Continuity was restored with a gastric conduit and a cervical anastomosis. RESULTS: A total of 18 (86%) procedures were completed thoracoscopically. The operating time for the thoracoscopic phase was 180 min (range, 120–240 min), and the median blood loss was 400 ml (range, 150–700 ml). A median of 20 (range, 9–30) lymph nodes were retrieved. The median intensive care unit stay was 4 days (range, 1–129 days), and the hospital stay was 18 days (range, 11–182 days). Pulmonary complications occurred in 10 patients (48%), and one patient (5%) died of a tracheone-oesophageal fistula. CONCLUSION: In this initial experience, robot-assisted thoracoscopic esophagectomy was found to be feasible, providing an effective lymphadenectomy with low blood loss. Standardization of the technique and increased experience should reduce the complication rate, which is in the range of the rate for open transthoracic dissection (Van Hillegersberg, et al., 2006).	
		4 2005	Report of the initial experience with the application of robotic-assisted technologies to the treatment (e.g. thymectomy) of diseases of the anterior mediastinum. 18 consecutive patients with anterior mediastinal masses were referred for diagnosis and treatment. A single surgical team performed all operations. Resection was accomplished by either median sternotomy or robotic-assisted techniques. 14 patients underwent successful robotic-assisted thymectomy. 1 patient underwent robotic-assisted biopsy of a mass that was later determined to be a poorly differentiated carcinoma. No conversions, intraoperative complications, or deaths occurred in the 15 patients who underwent robotic-assisted resection. The mean operative time was 96 minutes (range 62 to 132 minutes). The mean robotic time was 48 minutes (range 22 to 76). The median hospital stay was 2 days. All patients are doing well, with a median follow-up of 1 year. Robotic-assisted surgery of the anterior mediastinum, and particularly thymectomy, is feasible and seems safe and efficient. The increased visualization and instrument dexterity afforded by this technology provides an optimal minimally invasive approach to the anterior mediastinum. From this experience a	

			comprehensive treatment algorithm for the surgical evaluation and treatment of patients with anterior mediastinal diseases was formulated (Savitt, et al., 2005).	
		4 2004	Report of the experience of a single institution with the minimally invasive resection of mediastinal masses using the da Vinci robotic surgical system. 14 patients (5 men and 9 women aged from 21 to 77 years) with mediastinal masses were operated. This consisted of 9 thymectomies (6 thymomas, 2 nonatrophic thymic glands, 1 thymic cyst), 3 resections of paravertebral neurinomas, 1 ectopic mediastinal parathyroidectomy, and 1 resection of a lymphangioma. RESULTS: Complete, extended thymectomy was accomplished in all 9 cases, proven by examination of the thymic bed and resected specimen. In 1 patient with an hourglass-shaped neurinoma, conversion to an open procedure was necessary because the excessive size of the tumor limited vision. The median overall operating time was 166 minutes (range, 61 to 182) including 110 minutes (range, 46 to 142) for the robotic act. There were no intraoperative complications or surgical mortality. CONCLUSIONS: These preliminary results suggest that application of the da Vinci robotic surgical system for resection of selected mediastinal masses is technically feasible and safe. It provides an alternative to open approaches and "conventional" thoracoscopy. Nevertheless, this new technique requires further investigation in larger series and longer follow-up (Bodner, Wykypiel, Wetscher, & Schmid, 2004).	
		4 2006	Video-assisted thoracic surgical lobectomy with the da Vinci Surgical System was attempted in 34 patients (median age, 69.0 years; age range, 12-85 years). Robotic instruments were used for individual dissection of the hilar structures through 2 thoracoscopic ports and a 4-cm utility incision without rib spreading. Data on patient characteristics and perioperative results were collected prospectively. Robot-assisted video-assisted thoracic surgical lobectomy was accomplished in 30 patients (19 female and 11 male patients). Every type of lobectomy was performed. Four (4/34 [12%]) patients required conversion to thoracotomy. The majority of patients had non–small cell lung cancer (32/34 [94%]), and 1 patient had a typical carcinoid tumor and an extranodal B-cell lymphoma. Every patient underwent an R0 resection. The median number of lymph node stations dissected with robotic assistance was 4 (range, 2-7). Operative mortality was 0%, with no in-hospital or perioperative deaths. Nine (26%) patients experienced National Cancer Institute Common Toxicity Criteria for Adverse Events version 3.0 grade 2 or 3 complications. The median chest tube duration was 3.0 days (range, 2-12 days), and the median length of stay was 4.5 days (range, 2-14 days). The median operative time was 218 minutes (range, 155-350 minutes). CONCLUSIONS: Robot assistance for video-assisted thoracic surgical lobectomy	

			is feasible and seems safe. The utility and advantages of robotic assistance for video-assisted thoracic surgical lobectomy require further refinement and study of the technique (Park, Flores, & Rusch, 2006).	
		4 2005	Robotic-assisted thoracoscopic surgery (RATS) using the da Vinci system was performed in 6 patients with esophageal tumors. This comprised the dissection of the intrathoracic esophagus including lymph node dissection in four patients suffering from esophageal cancer and the extirpation of a benign lesion (one leiomyoma and one foregut cyst) in the remaining two patients. All procedures were completed successfully with the robot. The median overall operating time was 173 (160–190) minutes in the oncologic cases and 121 minutes in the benign cases, including the robotic act of 147(135–160) minutes and 94 minutes, respectively. There were no intraoperative complications. 1 patient had to undergo a redo thoracoscopy because of a persistent lymph fistula. 1 cancer patient died after 12 months due to tumor progression and another patient had to be stented due to local tumor recurrence 19 months postoperatively. This first small series of various esophageal pathologies treated by robotic-assisted thoracoscopic surgery supports the impression that the esophagus is an ideal organ for a robotic approach. The potential of the da Vinci system, especially for oncologic indications, remains to be proven in future clinical trials (Bodner, et al., 2005).	
	Indications			
	Population affected			Epidemiological information is available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization			
	Effectiveness			
	Social Outcomes			
	Safety			
	Efficacy			
Economic elements	**Efficiency**			
	Costs			

Patient Related elements	**Patient-related juridical aspects**			
	Ethics			
	Psychological reactions			

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Clinical elements	**Applicability**	4 2008	27 patients underwent robotic-assisted laparoscopic radical cyctectomy. Indications were muscle-invasive transitional cell carcinoma (TCC) or leiomyosarcoma of the urinary bladder (n=24) and bladder shrinking following prior radiotherapy for TCC (n=3). A pelvic lymphadenectomy was routine part of the procedure. Mean operating time: 340 min (range 150-450). Mean number of lymph nodes retrieved was 23. 1 case of surgical margins. Data follow-up (mean 10.2 months): 2 perioperative and 3 portoperative complications; 6 of 7 nerve-sparing surgerypatients reported satisfying erectil function. After a mean of 3.5 months day-time continence was completely restored in 7 of 8 patients. This seems a feasible procedure (Mottrie, et al., 2008).	
		4 2008	15 patients with a rectal prolapse underwent robot-assisted laparoscopic rectovaginopexy. Parameters: operating time, blood loss, intra-operative and postoperative complications, and outcome at a minimum of 1 year after surgery. Operating time (skin-to-skin): 160 min (range 120-180); no conversions to open surgery; no in-hospital complications; no mortality, median hospital stay: 4 days (range 2-9). Follow-up: 2 surgical reinterventions within 3 months after surgery; one year after surgery 87% of patients claimed to be satisfied. This applications seems feasible (Draaisma, Nieuwenhuis, Janssen, & Broeders, 2008).	
		4 2008	A total of 12 patients underwent robotic-assisted laparoscopic ureteral reimplantation. The indications for ureteral reimplantation included ureteral stricture (n=10) and ureterovaginal fistula (n=2). 9 patients had pathology on the	

Urologic Surgery				
Main Elements	Variables	Oxford's level of evidence and year of publication	Results	Remarks
			left side and 4 patients had right-sided disease. Surgery was performed by three experienced laparoscopic robotic surgeons. Mean operative time was 208 min (80 - 360 min). Mean robot time was 173 min (75 - 300 min). Mean estimated blood loss was 48 mL (45 - 100 mL). The mean length of hospital stay was 4.3 days (2 - 8 days). All the procedures were completed successfully robotically without open conversion. There were no intraoperative or postoperative complications. Postoperative intravenous urography and Mercapto Acetyl TriGlycine 3 showed normal findings in 10 patients and a mild residual hydronephrosis in 2 patients. After a mean follow-up of 15.5 months, all patients were asymptomatic of their initial disease state. This multi-institutional, multinational experience illustrates that ureteral reimplantation with psoas hitch is feasible to treat lower tract ureteral obstruction (Patil, Mottrie, Sundaram, & Patel, 2008).	
		4 2006	13 patients underwent robotic extended pyelolithotomy for treatment of renal calculi. Complete stone removal was accomplished in all patients except one with a complete staghorn calculus. REP is a feasible treatment alternative next to (Percutaneous nephrolithotomy) PCNL for patients with staghorn calculi (Badani, et al., 2006).	The feasability of treatment of complete staghorn stones using the robot system acquires further research.
		2A 2007	Robot-assisted laparoscopic adrenalectomy seems technically feasible, but agreement on the advantages over laparoscopic has yet to be reached (Thaly, Shah, & Patel, 2007). Different studies report different results in operative time, morbidity, conversion to standard laparoscopic or open adrenalectomy, and costs (Thaly, et al., 2007; Horgan & Vanuno, 2001 as cited in Thaly, et al., 2007; Winter et al., 2006 as cited in Thaly, et al., 2007; Bentas, Wolfram, Brautigam & Binder, 2002 as cited in Thaly, et al., 2007; Desai, et al., 2002 as cited in Thaly, et al., 2007; Bunaud, et al., 2003 as cited in Thaly, et al., 2007; Beninca, Garrone, Rebecchi, Giaccone, & Morino, 2003 as cited in Thaly, et al., 2007).	
		2A 2007	Robotic radical cystectomy is still in the developing phase (Miller, & Theodorescu, 2006; Thaly, et al., 2007). In this procedure there are 2 components mandatory: the extirpative surgery (radical cystectomy) and the reconstructive surgery for urinary diversion (Thaly, et al., 2007). This procedure is not free from complications, especially if diversion is performed totally intracorporeally (Hemal,	

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			Kumar, Seth, & Gupta, 2004 as cited in Thaly, et al., 2007; Goel, 2004 as cited in Thaly, et al., 2007). Early experiences have shown promise for future innovation, but feasability results are still unclear (Miller, & Theodorescu, 2006; Thaly et al., 2007).	
	Indications	5 2008	The indications for robot-assisted radical prostatectomy (RALP) are not different from conventional or laparoscopic prostatectomy. The indication is a localized prostatecarcinoma within a patient with a life-expectancy of >10 years. Surgeries in the past that occurred in the same area of the body, can hamper endoscopic access (Horenblas & van der Poel, in press).	
		3A 2006	The standard indications for LRP or RALP in prostatectomy do not differ from that of RRP. Neither are there anatomical contraindications for LRP or RALP (Rozet, Harmon, Cathelineau, Barret, & Vallacien, 2006).	
	Population affected			Epidemiological information is available, but this is highly depending on the diagnosis. There are too many diagnoses in this specialty to mention.
	Utilization	5 2008	The utilization of the robot is increased in the Netherlands and is most used in urology (Result semi-structured interviews).	
	Effectiveness	3A 2007-2008	There are 3 case series with small population (n=12 (Phillips, Taneja, & Stiffelman, 2005 as cited in Thaly, et al., 2007), n=13 (Gettman et al., 2004 as cited in Thaly, et al., 2007) and n=10 (Kaul, et al., 2007)), 1 case study (Pedraza, Palmer, Mos, & Franco, 2004 as cited in Thaly, et al., 2007), 1 cohort-control study (Caruso, Phillips, Kau, Taneja, & Stifelman, 2006 as cited in Thaly, et al., 2007) (n=20) and 1 multi-institutional case serie (Thaly, et al., 2007) with a larger population (n=148). All case series performed robot-assisted laparoscopic particial nephrectomy (RALPN). It is difficult to compare the results, because they do not report the same parameters or used different definitions. Mean operative time was 311 min. Mean warm isschemia time was 25.4 min. Mean blood loss was 141 mL. In 79% there was artery clamping. All series had similar results. When comparing these results to a standard laparoscopic particial nephrectomy,	Adoption of robotic radical nephrectomy has not occurred as quickly as with prostatectomy, probably because the technical advantages are not often needed during nephrectomy (Thaly, et al., 2007).

Urologic Surgery				
Main Elements	Variables	Oxford's level of evidence and year of publication	Results	Remarks
			the results seem similar (Thaly, et al., 2007). RALPN is feasible and reproducable, but the overall advantages over conventional laparoscopic particial nephrectomyare still unknown (Thaly, et al., 2007).	
		2A 2007	The largest serie (n=55) had an 11 months follow-up (Thaly, et al., 2007). They performed a robot-assisted Anderson-Hynes dismembered pyeloplasty. Most patients were discharged on postoperative day 1. The ureteral stents were removed within 3 weeks. There were no complications and minimum blood loss (<50mL). 96% had objective and subjective improvement. The other series report similar results (Gettman, Neururer, & Bartsch, 2002 as cited in Thaly, et al., 2007; Gettman, Peschel, & Neururer, 2002 as cited in Thaly, et al., 2007; Peschel, Neururer, & Bartsch, 2004 as cited in Thaly, et al., 2007; Siddiq, Leveillee, & Villicana, 2005 as cited in Thaly, et al., 2007; Palese, Stifelman, & Munver, 2005 as cited in Thaly, et al., 2007; Patel, 2005 as cited in Thaly, et al., 2007). Robot-assisted pyeloplasty compared to laparoscopic pyelopasty had a shorter mean operative time and shorter suturing time, but blood loss, hospital stay and complications are similar (Thaly, et al., 2007; Peschel, Neururer, & Bartsch, 2004 as cited in Thaly, et al., 2007). The overall advantages of robot-assisted pyeloplasty over laparoscopic are still unknown.	
		2A 2007	This review compares robotic-assisted radical prostatectomy (RALP) with radical retropubic prostatectomy (RRP). Effectiveness of prostatectomy can be operationalized in blood loss/transfusion, length of hospital stay, postoperative pain, continence, potency, oncologic outcomes and complications. *Blood loss and transfusion:* Reduced intra-operative blood loss has been regarded as one of the hallmark advantages of laparoscopic prostatectomy (Pasticier, Rietbergen, Guillonneau, Fromont, Menon, & Vallancien, 2001 as cited in Thaly, et al., 2007). Transfusion after robot-assisted radical prostatectomy (RALP) has been reported to be 0-17%. Radical retropubic prostatectomy (RRP) has a significantly higher rate of transfusion (67%) (Tewari, Srivasatava, & Menon, 2003 as cited in Thaly, et al., 2007). The mean estimated blood loss in the RALP series was 75mL (10-900mL) (Thaly, et al., 2007), with most <200mL (Thaly, et al., 2007). A more recent report mentioned a mean of 100mL (Badani, Kaul, & Menon, 2007).	The Sexual Health Inventory for Men (SHIM) seems to be the most valid instrument to study potency. More research is necessary about the post-operative pain and oncologic outcomes after RALP. A large randomized control trial (RCT) is necessary to assess the overall advantages of RALP over RRP.

Urologic Surgery				
Main Elements	Variables	Oxford's level of evidence and year of publication	Results	Remarks
			Length of hospital stay: RRP has usually a hospital stay of 1-3 days (Thaly, et al., 2007). RALP has a mean of 1.08 – 1.5 days, declining with increased surgical experience (Menon, Tewari & Peabody, 2003 as cited in Thaly, et al., 2007; Ahlering, et al., 2003 as cited in Thaly, et al., 2007; Menon et al., 2002 as cited in Thaly, et al., 2007; Wolfram et al., 2003 as cited in Thaly, et al., 2007; Ahlering, Woo, Eichel, Lee, Edwards, & Skarecky, 2004 as cited in Thaly, et al., 2007; Patel, Tully, Holmes, & Lindsay, 2005 as cited in Thaly, et al., 2007). RALP has significantly a shorter mean length of hospital stay (Tewari, Srivasatava, & Menon, 2003 as cited in Thaly, et al., 2007; Ahlering, Skarecky, Lee, & Clayman, 2003 as cited in Thaly, et al., 2007). A more recent report mentioned similar results with 96,7% of the patients that leaves the hospital within < 24 hours (Badani, et al., 2007). *Postoperative pain:* There are conflicting reports about postoperative pain of RALP compared with RRP. Menon et al (2005) reported a significantly difference between postoperative pain after RALP or RRP (Morgan, et al., 2005; Menon, et al., 2005). Webster (2005 as cited in Thaly, et al., 2007) reports the converse with no statistical difference in pain. *Continence:* Most series report 90-95% continence 12 months after RRP (Thaly, et al., 2007). After 3 months this is in a range of 50-76% (Ahlering, et al., 2004 as cited in Thaly, et al., 2007). RALP seems to have a faster recovery of continence with 33% in 1 week and 63% in 1 month (Thaly, et al., 2007). A recent report of a hughe cohort study (n=2766) even reports a continence of 23.7% within 1 day and within 28 months 93% (Badani, et al., 2007). Long-term results seem to be similar, but RALP seems to have a faster recovery. An unpublished report of a recent cohort study (n=147) mentioned that fascia preservation at the lateral aspect of the prostate is the best predictor of any urinary continence after RALP (Van der Poel, De Blok, & Van Muilekom, in press). A recent cohort-control study using "haphazard assignment" concludes that median fibrous raphe suspension does not improve early post-prostatectomy urinary continence (Van der Poel, De Blok, & Van Muilekom, in press). *Potency:* Potency outcomes are difficult to compare across series because of differences in definition of potency and patient selection. Overall potency of RRP is reported to be 86% after 18 months (Thaly, et al., 2007). RALP has a more rapid return of erection and intercourse (Badani, et al., 2007) and has a potency	

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			of 97% after 1 year (Thaly, et al., 2007). Younger age, better pre-operative potency and extend of neurovascular bundle preservation are affecting post-operative return of erectile function (Catalona, Carvalhal, Mager, & Smiths, 1999 as cited in Thaly, et al., 2007). RALP has higher rate of preservation of neurovascular bundles (Fagin, 2007). Oncologic outcomes: Overall margin positive rates (MPR) of RRP are in a range of 0-77% with an overall average of 28% (Wieder & Soloway, 1998 as cited in Thaly, et al., 2007). The reported MPR after RALP series range from 0-36% (Thaly, et al., 2007; Badani, et al., 2007; Mottrie, et al., 2007) with an decrease correlated with experience (Van der Poel & De Blok, in press). These reports with surrogate markers, e.g. PMR and prostate-specific antigen (PSA) recurrence data, are promising for RALP, but long-term outcomes are currently unavailable. The procedure with PSA is only 6 years old and is immature. For RALP to be accepted as a satisfactory alternative to current best practice, oncologic outcomes must be proven to be uncompromised (Thaly, et al., 2007; Ahlering, et al., 2003 as cited in Thaly, et al., 2007). *Complications:* A recent study of complications of RALP using the Clavien's classification of surgical complications concludes that the overall robotic complication rate is very low and appears to be even less than in open series (Fischer, Engel, Fehr, & John, 2008; Badani, et al., 2007). Minor and major complications seem to decrease after an experience of 200 surgeries (Fischer et al., 2008). CONCLUSIONS: RALP has decreased blood loss, hospitalisation and complications compared to RRP. RALP has a more rapid return of continence, erection and intercourse. More research is necessary about the post-operative pain and oncologic outcomes. The overall advantages of RALP over laparoscopic prostatectomy are still unknown.	
		3A 2006	This review compares robotic-assisted radical prostatectomy (RALP) with laparoscopic radical prostatectomy (LRP) (Rozet, et al., 2006). Effectiveness of prostatectomy is measured in blood loss/transfusion, length of hospital stay, continence, potency, oncologic outcomes and complications. *Blood loss / transfusion:* The estimated blood loss for LRP averages 482 ml (185-	A large randomized control trial (RCT) is necessary to assess the overall advantages of RALP over LRP.

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
			850 ml) versus 234 ml (75-500 ml) for RALP. *Length of hospital stay:* There is no significant difference between the number of days spent in the hospital between LRP and RALP. *Continence:* Continence outcomes for LRP ranges from 56 – 100%, but no follow-up time is mentioned. Another problem is the variety of definitions of continence, which makes adequate comparison difficult. Continence outcomes for RALP were not available at the time of the review. *Potency:* no data *Oncologic outcomes:* Long term outcomes data on PSA progression were not yet available at the time of the review due to the relative short existence of the method. There seem no significant difference between LRP and RALP groups in terms of overall positive surgical margins. *Complications:* The overall complication rates show large discrepanties between the series. CONCLUSION: Intra-operative and post-operative outcomes apear to be comparable between RALP and LRP. Longer follow-up data are necessary to compare oncological and functional outcomes (Rozet, et al., 2006).	
	Social Outcomes	4 in press	In a recent study about the influence of the learning curve of RALP on oncologic results and Quality of Life (QoL) there was a possitive correlation. The learning curve is characterized by an improvement of oncological results and, to a lesser extent, QoL as assessed by validated patient recorded questionnaires (Van der Poel & De Blok, in press). Another cohort study (n=108), of the same authors, reveiled that most patients returned to their baseline level of QoL within 6 months after RALP. A decrease of QoL was correlated with voiding problems. Of the men that scored a reduction in sexual function, 74% reported that their sexual activity returned to baseline after RALP (Van der Poel, De Blok & Van Muilekom, in press).	
		5 2008	One surgeon mentioned: “Robot-assisted prostatectomy has a positive social-environmental impact: earlier return to home and work due to shorter hospital stay and less incontinence. Also less potency problems affect relationships positively” (Result semi-structured interviews)	
	Safety			

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
	Efficacy			
Economic elements	**Efficiency**	5 2008	A lot can be improved in logistics concerning the use of the DaVinci in the Netherlands. There have been/are problems with avalaible operationtime and planning for RALP. Citations from interviews with 5 surgeons in the Netherlands: "We started a study/project to analyze on which disposables we could save." (no data available). "We started a project regarding the efficiency of usage of the robot and available operating time." (Result semi-structured interviews)	
		2A 2007	Robot-assisted pyeloplasty compared to laparoscopic pyelopasty had a shorter mean operative time and shorter suturing time (Thaly, et al., 2007; Gettman, Peschel, & Neururer, 2002 as cited in Thaly, et al., 2007).	
		2A 2007	This review compares RALP with RRP. The operative time is difficult to compare due to different definitions. The mean operating time for robot-assisted radical prostatectomy (RALP) ranges from 90-540 min. and decreases with experience (Thaly, et al., 2007). A more recent report even mentioned an operative time of 75 min. using a specific technique for RALP: athermal combined anterior and posterior dissection technique with clips and sharp dissection alone (Boggess, 2007). There is no significant difference between radical retropubic prostatectomy (RRP) and RALP for experienced surgeons.	
		3A 2006	This review compares robotic-assisted radical prostatectomy (RALP) with laparoscopic radical prostatectomy (LRP) (Rozet, et al., 2006). *Operating time:* The average time across series for LRP is 234 min (151-453 min). Operative times from RALP range from 141 – 250 min with an average across series of 182 min. In several single institution series no statistically difference was observed.	
	Costs	5 2008	The costs are administrated in all 5 hospitals for RALP. They are not analyzed yet (Result semi-structured interviews). Citations from interviews with 5 surgeons in the Netherlands: "The cost-effectiveness is being measured from now on. I do not think the robot is cost-effective." "The DaVinci is overpriced due to the monopoly."	Research question for the future: How much money will you spend for better quality / outcome?

Urologic Surgery				
Main Elements	**Variables**	**Oxford's level of evidence and year of publication**	**Results**	**Remarks**
Patient Related elements	**Patient-related juridical aspects**			
	Ethics			
	Psychological reactions	5 2008	Citations from interviews with 5 surgeons in the Netherlands: “Patients want the robot. Patients who fear the robot go to another hospital.” “Patients are attracted by the robot.” “Educating patients is very important. Patients need to get answers on all their questions about the robot. A surgeon needs to be prepared on that.” (Result semi-structured interviews)	Future research question: Why are patients not afraid of robotic-assisted surgery?

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