

Research report

Da Vinci Surgery: Is It a No-brainer?

Robot-assisted Prostate Surgery in the Mirror of Social Health Insurance

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'No-brainer' is an informal expression, which means anything that requires little thought or even no mental effort. The term is often applied to decisions which are straightforward and are absurdly simple to take.

(Source: online encyclopaedia www.encyclo.nl)

Summary

Context

In the Netherlands, managing the statutory benefits package is the task of the Health Care Insurance Board (*College voor zorgverzekeringen*; CVZ). CVZ has conducted research on the dynamics of the demand for medical-technological innovations. This is important for CVZ because many innovative forms of care stream freely into the benefits package (i.e., without CVZ's explicit assessment). They are 'automatically' insured care since they are actually used in practice. This makes it relevant for a benefits package manager to study the motives for demanding health care innovations. These motives are expressed by a 'sense of need' among stakeholders in the context of care delivery. In the current market-oriented context of care delivery, the sense of need is an important driver of actual service utilisation. It exerts influence on decisions to purchase (whether to use), to implement (how to use, and how often to use) and to request the new therapy.

Using a qualitative methodology, this case study explored the sense of need to purchase and implement an innovative surgical device called the da Vinci robot for the removal of prostate cancer (Robot-assisted Radical Prostatectomy; RARP). It is a promising innovation despite its high costs and its as yet unproven superiority over existing treatment alternatives.

Results

The sense of need for RARP is constructed in the interconnection between the stakeholders involved, namely, the manufacturer, care-providers (including scientific communities), receivers (patients) and insurers (payers). At the heart of this need lies the subjective perception of the benefits of the new therapy which can be described as follows: the premise of progress, performing better than the competition (gaining prestige and perhaps profits), a transition platform towards minimally invasive surgery, considerable research opportunities (contributing to the clinical/technical science surrounding the da Vinci robot), technical precision and perceived improved ergonomics of operating with the da Vinci system.

Constant reproduction of these benefits within the network of stakeholders perpetuates the sense of need and drives them to demand the RARP as 'the way to go'. To that end, those faced with the choice of purchasing the apparatus, working with it, or undergoing surgery with it may rationalise (cognitively regard, articulate, and advocate) what they 'want' as what they 'need'. Promotion by the manufacturer and the mass media's seductive image-building of the da Vinci system feed this process. After purchasing and during the course of implementation, the sense of need to purchase is replaced by

a subsequent perception of pressure (marked sense of need) for constantly extending use of the robot to enhance surgical skills, produce more scientific evidence, and more notably, to meet the break-even point for costs. Within the context of care delivery, the da Vinci system offers stakeholders the capacity to increase not only therapeutic productivity (state of the art surgery), but also scientific (clinical research), technical (device development) and economic (profit/status) productivity. Once stakeholders conceptualise the benefits of RARP in this way, they become inclined to demand and use the da Vinci system with an ever-growing frequency.

Discussion

The case study of RARP signals a potential risk that insufficient discerning attention is being paid to the real (additional) benefits of technological innovations. Failing to counterbalance this will drive up health care costs as well as hampering optimal utilisation of collective resources. In particular, there may be the risk of service overuse (over-treatment) and misallocation of capacity by oversupplying some services and undersupplying others. In so far as the care is part of the benefits package, the costs are largely at the expense of the social health insurance and thus borne by citizens.

This signifies the capacity of benefits package management to influence the sense of need and regulate demand. Benefits package management, when used as a regulatory instrument, is not intended to slow down innovation and enterprise in health care. On the contrary by its very nature, it facilitates diffusion of innovations, their broader utilization, and their further (incremental) developments. Influencing the sense of need by means of package management may have an important impact. It may ensure meeting a realistic demand whilst optimising the health gains for the Euros spent by the Social Health Insurance system. However, perhaps the latter is also a 'no-brainer'.

1. SUBJECTING THE DA VINCI ROBOT SURGERY TO AN AUDIT

1.a. Introduction

Benefits package management in the Netherlands

The statutory health care benefits package forms the heart of the Dutch social health insurance system. It is enacted within a legal framework comprised of the Health Care Insurance Act (*Zorgverzekeringswet*; Zvw) and the Exceptional Medical Expenses Act (*Algemene Wet Bijzondere Ziektekosten*; AWBZ). In the Netherlands, managing the statutory benefits package is the task of the Health Care Insurance Board (*College voor zorgverzekeringen*; CVZ). CVZ is a non-departmental government organisation responsible for the implementation of the social health insurance. One of CVZ's tasks is to advise on the content of the benefits package and reimbursement of care in that package. CVZ's advice regarding the inclusion of care in the benefits package, or its removal, is addressed to the Ministry of Health. In other cases its advice may involve an explanation of which care is insured and will be addressed to private health insurers. Forms of care designated as collectively insured care are then reimbursed via the Social Health Insurance Fund.

Benefits package management as a governance tool

Whether new forms of care are adopted in practice will in many cases depend on whether they are included in the benefits package. This is because inclusion in the package will guarantee finance for the care involved and facilitate its adoption and utilisation. Conversely, not being included in the package can result in a certain form of care being used less or not at all in practice. Managing the benefits package, and in particular, reimbursement decision-making, can therefore be seen as having a 'gatekeeper' function that is capable of ensuring the prudent introduction and diffusion of new forms of care.

The context of the Health Care Insurance Act (Zvw)

After the introduction of Zvw in the Netherlands (2006), hospitals and insurers were granted an increased degree of freedom of choice to finance and provide many non-urgent forms of curative care (the so-called B-segment of curative care). This is particularly important for care provided by medical specialists, which involves advanced and often expensive new forms of care. This is where most scientific and technological developments take place. Very often these forms of care simply stream into the benefits package because they are actually used in clinical practice. In fact, the decisions of hospitals and professionals to provide the majority of innovations 'automatically' ensure that they get reimbursed. Innovations within medical specialty care constitute a major influx into the benefits package without being subjected to (prior) reimbursement assessment. Only in few cases does CVZ come into the picture if there is some doubt about the (cost-)

effectiveness of a form of care. This makes it relevant to study the way innovations are introduced into a medical specialty/hospital care. Once freedom of provision is granted within a competitive market-oriented context, the dynamics of demand forms the subsequent issue that should be explored by a benefits package manager.

Auditing the demand for health care innovations

A demand for a new form of care exists when individuals consider that they have a need and wish to receive or utilise it (Culyer 2007). Demand as such is characterised by a sense of need (so-called felt need or perceived need) (ibid.). This perceived need directs individuals to arrive at certain decisions or take certain actions (behaviours), for instance, decisions to adopt (purchase) or request a new therapy or utilise an innovation in a certain way and to a particular degree (volume). The perceived need is, therefore, an expression of demand in its cognitive and/or literal sense, although the sense of need can be seen as a supply-side concept in the economic sense (ibid.). In this report, the word 'demand' is used interchangeably with 'sense of need'.

The sense of need for a health care innovation plays an essential role in all stages of decision-making about a new form of treatment: its purchase, its introduction, its use by providers and/or by patients. At the heart of this perceived need are the 'demonstrated benefits' of the new therapy, or simply, the reasons why someone would consider using it or receiving it. These benefits are established in a dynamic process involving constant interactions between stakeholders. These stakeholders include four main parties: manufacturer(s), care-providers, receivers (patients) and payers (private insurers). They are the 'social actors' and 'decisional bodies' within the context of care delivery. Their perspectives and interactions – ranging from publicity by the manufacturer up to the feedback of end-users – influence the way the benefits of new therapies are constructed and perceived by other actors, especially when there is still insufficient evidence available to establish their effectiveness. In other words, the benefits of health care innovations are not merely based on a set of pre-existing facts that are simply 'out there'. Rather, they are performative, constantly constructed and demonstrated in the web of interactions between stakeholders.

Auditing the drivers of (service) use

Since the perception of need implies rational and cognitive reasoning on the part of the stakeholders, it often remains attitudinal, abstract and implicit. Nevertheless, it continues to exert influence on decisions to purchase (whether to use), to implement (how to use and how often), and to request new therapy. To a benefits package manager, these are highly relevant because they are motives for adopting and diffusing an innovation and determine both the pattern and the degree to which a service is utilised. Moreover, the fact that the sense

of need is abstract and difficult to measure implies that it remains an under-studied issue from the perspective of social health insurance. It is difficult to subject the perception of need to regular auditing processes (quantification and measurement). Auditing concepts like this requires an in-depth 'understanding' instead. It requires an understanding of various perspectives, incentives and interrelationships that determine 'why' and 'how' innovations come to be adopted, diffused and implemented, particularly when other alternative forms of care already exist.

An in-depth understanding

An in-depth understanding of the way in which the need for innovative care originates and develops is of the utmost importance to a package manager. However within CVZ, this has not yet been properly conceptualised, neither in the assessment phase nor in the appraisal phase of reimbursement evaluations. Understanding the construction of need for a new therapy became even more relevant to CVZ recently. This relates to an important theme currently on the agenda of benefits package management, namely, Appropriate Use of Services (*Gepast Gebruik*). This ensures access to health care services for all those for whom care is really necessary. Appropriate Use of Services can lead to an efficient utilisation of the collective health insurance fund. If there is a need to optimise utilisation of scarce resources in health care, then there is a need to study the need for care.

1.b. Point of departure: an empirical research project

Identification of a 'case study'

In order to understand the construction of need, a conceptual model of the context of care delivery was first designed (figure 1). This model is about the relationships between stakeholders, the role they play and the influence they have on the contents of the basic package. This model was then applied to a new form of care in order to make a concrete case study. A case study as such can be a method of choice for an in-depth examination of the complex interaction between a phenomenon and its "real-life" context (Yin 1994). The idea is to arrive at a fundamental understanding of the sense of need. It is designed to provide a 'thick description' (in-depth clarification) of the origin and development of the need, focusing on decisions, interactions and dynamics in demanding a given new form of care.

The 'case' (the main unit of study) identified was a new surgical procedure for treating patients with localised prostate cancer known as robot-assisted radical prostatectomy (hereafter referred to as RARP). It involves the surgical excision of a cancerous prostate gland and surrounding tissues with

the help of a state-of-the-art laparoscopic device called the da Vinci robot. The following sections provide a detailed description of this therapy as well as alternative surgical forms of treatment. First, the study design is discussed.

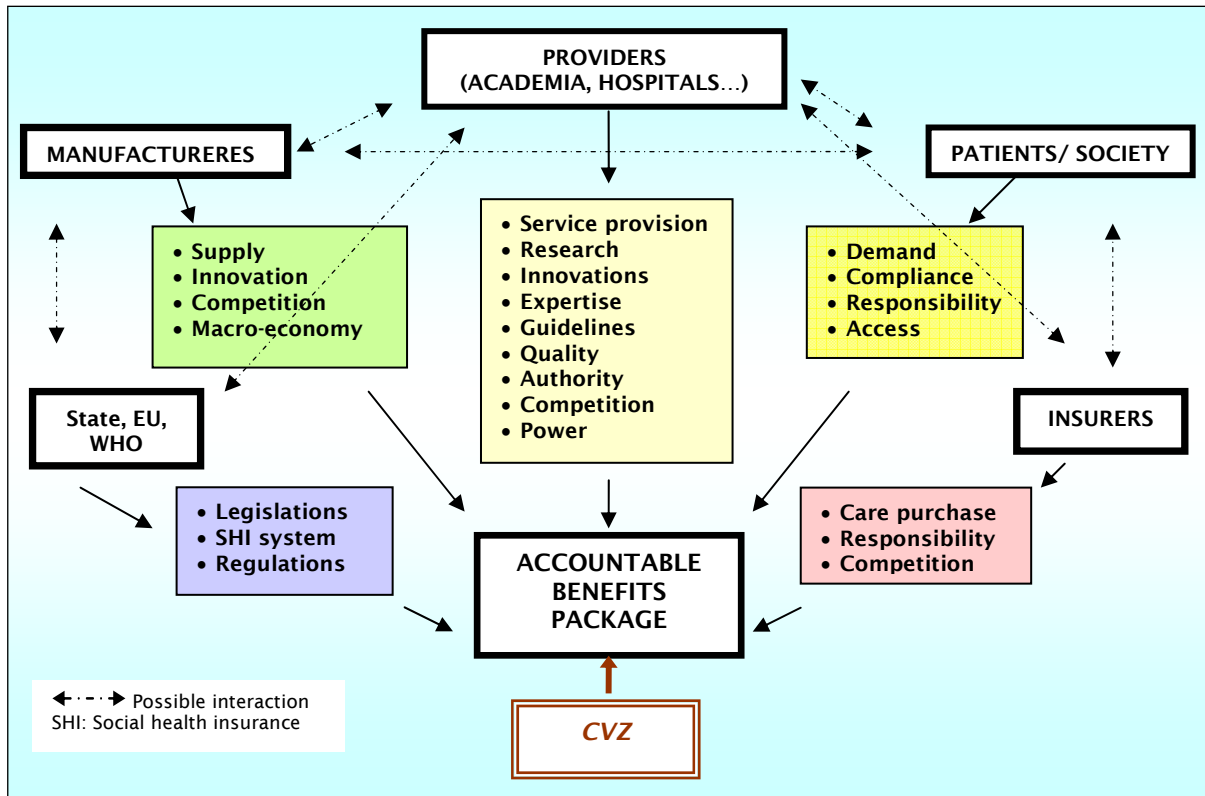


Figure1. A conceptual model of the context of care provision in relation to the benefits package

Justification of the case

The da Vinci device provides a ‘rich case’ to study empirically the dynamics of the need for a new form of care such as RARP. The reasons why the RARP is a suitable case for this study are as follows:

- At the moment, the da Vinci system is in the diffusion phase in the Netherlands. Some hospitals are currently using this system and others are considering purchasing it. Exploring the sense of need for the da Vinci system at this point provides us with an array of arguments about the perceived benefits of RARP that account for both ‘shaping’ and ‘meeting’ the demand. By bring together these arguments we can understand the entire process of the origin and development of the need for the da Vinci system in a single case study.
- The da Vinci system is regarded as a highly promising innovation. It has been received with profound enthusiasm by a growing number of surgeons (particularly urologists) and

hospitals in Europe and the US. This enthusiasm must be driven by a strong perception of the added value of the device. The costs are nevertheless high and less expensive alternatives are available. This means that the arguments in favour of the da Vinci device must be quite convincing. What arguments/considerations are being used to justify needing this particular treatment? How are the advantages being defined and understood by the stakeholders involved?

- The core element of this surgical treatment is a state of the art device that allows the surgeon to carry out the operation remotely. In general, the field of medical/surgical devices has clearly been subject to less study in comparison with pharmaceuticals (Faulkner 2009). Within the Dutch context, medical devices are subject to less reimbursement assessment than, for instance, new pharmaceuticals in terms of both efficiency and comparative effectiveness.¹ Unlike pharmaceuticals, no exclusive list of predefined items (positive list) applies to this sub-sector of care. This makes the RARP a suitable case for obtaining more insight in the field of medical devices.
- Worldwide, the da Vinci system has been used most commonly in the field of urology for the surgical removal of prostate cancer (Murphy et al. 2008). This makes prostate cancer a suitable area for studying the need for the da Vinci system. Moreover, some alternative surgical and non-surgical methods do exist for treating prostate cancer (see the next section). Prostate cancer and its different treatment options are areas of ongoing debate in both the professional and the public arena (among urologists, in medical journals, on patients' forums and sometimes via mass media). It was stated, at the opening of the 2009 European Association of Urology (EAU) conference in Stockholm: "Figures vary around the world, but the fact remains: prostate cancer diagnosis and treatment continue to be the most pressing issue in onco-urolog[y]".
- Available studies on the clinical effectiveness of RARP cover a diverse range of arguments, some of them poorly substantiated and some inconsistent. Even the clinical significance of the generally acknowledged advantage of RARP, namely, a reduced chance of bleeding (compared with the conventional surgical method), has been questioned (Lepor 2005). Economic analyses also suffer from poor study design and existing uncertainty about clinical effectiveness (Camberlin 2009). This makes it difficult to draw a conclusive argument on the overall benefits of RARP. Despite a recent exponential increase in the number of publications about RARP (Middelbeek 2007), a 'lack of evidence of effectiveness' is still

¹ At the EU level also, market authorisation for medical devices does not necessarily require evidence of effectiveness or efficiency. Evidence of mechanical performance in a laboratory setting is sufficient for many devices to get approval at EU level for market entry (achieving a CE-mark). In addition, the comparative effectiveness of a new device (whether it performs better in terms of patient outcomes and whether it is substantially 'new' or almost equivalent to an existing device) is not part of the EU regulatory regime either (Faulkner 2009).

reported by, among others, two systematic reviews of the topic: Camberlin et al. (2009) and Ficarra et al. (2009). Studying the demonstrated benefits of RARP that are experienced in practice provides insight into its 'empirical' (cost-)effectiveness, which should contribute to completing the evidence.

- The above-mentioned reviews converge to the point that, at the moment, “no claims of superiority of robot-assisted surgical techniques can or should be made” (Camberlin et al. P: 37). This argument may not be congruent with what is happening in practice: the increasing utilisation rate of robotic surgery, particularly for prostate surgery. One can expect many 'claims of superiority' that justify this trend. This study aims to explore some of these claims of superiority within the Dutch context.

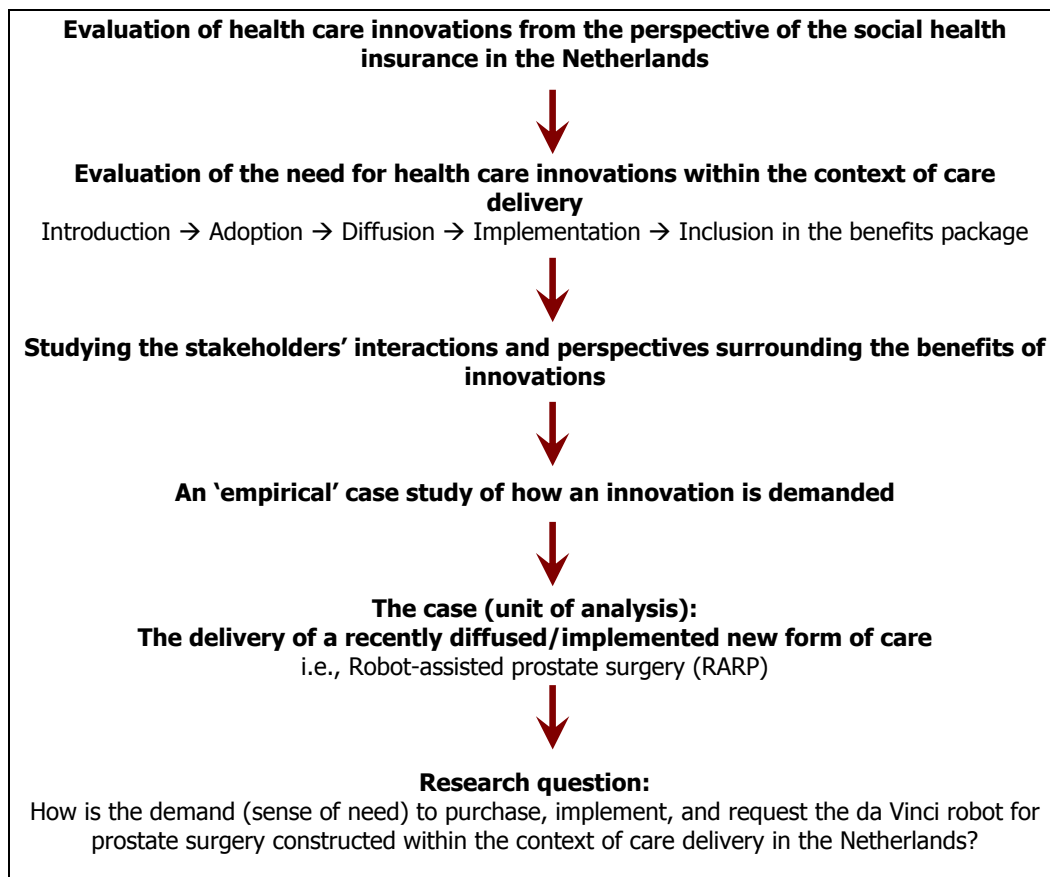


Figure 2: Design trajectory and concretisation of the research question

The objective and the main research question

Figure 2 shows the design trajectory of this study. It characterises how evaluation of health care innovations within the framework of the social health insurance can be completed by studying the demand for RARP as a prototype of high-tech health care innovations. With particular attention being paid to

stakeholders' perspectives, the main research question is:
How is the demand (sense of need) to purchase, implement and request the da Vinci robot for prostate surgery constructed within the context of care delivery in the Netherlands?

Study type and method

From a methodological point of view, evaluating the need for RARP may actually fall under the domain of Health Services Research (HSR). AcademyHealth, a professional resource for Health Services Research and health policy, defines HSR as a "multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and ultimately our health and well-being" (AcademyHealth 2010). HSR covers a wide range of methodologies. Since the primary emphasis of this study is on the stakeholders' interactions, perspectives and incentives, a sociological approach within the domain of HSR seems suitable. It draws on an empirical qualitative description inspired by insights from the field of Science and Technology Studies (STS)². This methodology may be a response to the call for a formal integration of the socio-political dimensions of health care technologies into reimbursement assessments (Lehoux & Blume 2000; Blume 2009; Sorenson et al. 2008; Kristensen 2009).

Study sample

A 'purposive' sampling method (Green 2005) was used to select informative, relevant, and willing respondents involved in delivering and receiving RARP. Approaching urologists was the starting point of the field research, though no strict rigor seemed necessary about the order of data collection from stakeholders. To enhance representativeness, a diverse sample of respondents was selected with a reasonable quantity from diverse geographical locations throughout the Netherlands. The study sample is reflected in table 1.

Data collection and data-gathering tools

Prior to field research, the author reviewed some of the medical literature as well as systematic reviews and technology assessment literature in order to understand the main lines of arguments about the (dis-)advantages of the da Vinci prostate surgery. He also familiarised himself with the surgical procedure, using multimedia resources. Data collection took place from April to July 2009. The main modes of data collection were in-depth semi-structured interviews and consulting some relevant Internet sources. Interviews took the form of either one-to-one or focus group discussions. An interview topic list was used to cover the main issues for interviews and adjusted accordingly during interviews. The

² STS is an interdisciplinary field of academic study. It examines the mutual influence of 'science & technology' and society. STS covers the division between social science and natural science. It can help us to link up the technological innovations with public policy.

discussion sessions lasted between one and 2.5 hours.

Generaliseability This study seeks to demonstrate a ‘conceptual generaliseability’ and ‘thick description’ of the construction of the need for RARP. Generalisation of individual perspectives is not the aim. Conceptual generaliseability relates to the transferability of concepts across similar settings, in knowing how far the findings help us to understand ‘what is going on’ in the field (Green 2005). Generaliseability here refers to the extent to which the results are applicable to understanding the formation of demand for other surgical devices or other technological innovations.

Respondents	Number of sessions of discussion	Descriptions
Urologists (personal interview)	8	<ul style="list-style-type: none"> • Robot surgeon: 3 • Laparoscopic surgeon: 2 • Open method urologist: 3
Patients with former prostate cancer	3	<ul style="list-style-type: none"> • Operated with robot: 1 • Operated with usual laparoscopy: 2
Prostate cancer patients’ organisation	1	<ul style="list-style-type: none"> • The respondent was a former prostate cancer patient, operated with usual laparoscopy
Hospital managers	3	<ul style="list-style-type: none"> • Academic medical centre: 2 • non-academic hospital: 1
Operation theatre nurse	1	<ul style="list-style-type: none"> • Assistant of a robotic urologist
Hospitals’ technical assistants	2	<ul style="list-style-type: none"> • Responsible for technical maintenance of the da Vinci robot
Care purchaser and medical advisor of health insurance companies	3	<ul style="list-style-type: none"> • Private insurance company: 2 • <i>Zorgverzekeraars Nederland (ZN)</i>: 1
Health care journalists	3	<ul style="list-style-type: none"> • Newspaper health care journalist: 2 • Freelance medical journalist: 1
Regulatory organisations	2	<ul style="list-style-type: none"> • Medical advisor of <i>De Nederlandse Zorgautoriteit (NZa)</i> • Advisor of the <i>DBC-Onderhoud</i>
Organiser of international medical congresses	1	<ul style="list-style-type: none"> • At European level
Particular Internet sources (among others)	NA	<ul style="list-style-type: none"> • Website of the Intuitive Surgical Inc. (the manufacturer of the device) • EAU annual conference website • Prostate cancer patient social networks, forums, and weblogs
Clinical epidemiologist	1	<ul style="list-style-type: none"> • Academic researcher
Total sessions of discussions	28	Including group interviews

Table 1. The study sample

Data analysis

Discussions were either recorded in minutes or digitally then transcribed verbatim. Transcripts were then checked for internal consistency (coherence of accounts); where inconsistency was found, the respondent was contacted for clarification. Since the researcher was not a native Dutch speaker, the discussions were conducted in English except for those with patients, which were conducted in Dutch and translated accordingly. Respondents were assured that identifying data, including the names of individuals and organisations, would be anonymised. The same was done to the information collected from Internet sources. Computer software for qualitative data analysis, called ATLAS.ti®, was used to process the primary data. Transcripts were then coded and categorised. Some minor abridgments of the respondents' accounts were applied to make transcripts anonymous and fit them correctly into the framework of written language. The data were then systematically analysed with a thematic content analysis approach.

The project was carried out by Payam Abrishami (physician and medical anthropologist, researcher of CVZ) and supervised by Professor Dr. Erik de Gier (expert in the field of social policy, linked to the School of Management, Radboud University, Nijmegen). The field study took approximately ten months, starting in March 2009.

1.c. The context: the treatment of prostate cancer

The prostate cancer

The prostate is an exocrine gland of the male reproductive system. Prostatic fluid constitutes a part of the volume of semen and supports sperms' survival and fertility. Prostate cancer is the most common form of cancer among Dutch men. It constitutes some 21 per cent of all cancers and 11 per cent of all deaths among men (RIVM). There are currently about 36 thousand patients with prostate cancer in the Netherlands (prevalence rate: 4.5 per thousand male population) and 7900 new cases in 2003 (incidence rate: one per thousand male population) (RIVM). In 2005, about half of the patients with prostate cancer were more than 75 years old (ibid.). Prostate cancer is currently the second cause of oncology-related death among men in the Western world (EAU conference webcast 2009).

Treatment

At the moment, treatment for prostate cancer involves six main categories that can be used solely or in combination: active surveillance (watchful waiting), surgery, radiation therapy (including brachytherapy and external beam radiation therapy), high-intensity focused ultrasound (HIFU), chemotherapy/hormonal therapy, and cryotherapy. The

presence of a tumour in the prostate may be suspected due to symptoms and/or a high level of a tissue indicator called prostatic-specific antigen (PSA) in a blood-test. The choice of treatment is determined according to the following general criteria: patient's age, his overall health status, cons and pros of each method for the individual patient, the patient's preference, and whether the cancer is localised in the prostate or has spread out. The latter criterion is judged based on a pathological indicator of cancer spread, namely the Gleason score.

This report focuses on the surgical treatment of prostate cancer, which has been shown to be an 'excellent treatment option' for localised prostate cancer (Martínez-Salamanca & Otero 2007). General criteria for opting for surgical treatment include: age younger than 70-75 years, lack of important co-morbidities, a life-expectancy of 10 years and longer, a Gleason score of 7 or less, and a PSA level less than 20 ng/ml³ (see also annex d.). At present, there are three different surgical approaches to removing a cancerous prostate gland. These are, in chronological order of emergence: open radical prostatectomy (ORP), laparoscopic radical prostatectomy (LRP) and robot-assisted radical prostatectomy (RARP). The last two approaches are considered minimally invasive surgeries (MIS). These techniques are described below.

Open radical prostatectomy (ORP)

Radical prostatectomy is an operation to remove the prostate gland entirely and some surrounding tissues, in order to stop the cancer from spreading further. In an ORP, the surgeon makes an incision of seven to nine centimetres in the lower abdomen to reach the prostate gland. For decades, open prostatectomy had been the method of choice to remove a cancerous prostate (Lepor 2005). ORP still remains the 'gold standard' therapy because of long term experience and patient follow-up. Thus, ORP has become a 'reference' in comparative studies on effectiveness, safety, costs, and outcome (Martínez-Salamanca & Otero 2007).

Laparoscopic radical prostatectomy (LRP)

LRP is the removal of the prostate gland with the use of a device called a laparoscope. A laparoscope is a device equipped with a camera to visualize inside the abdominal cavity. Typically, the laparoscope, as well as other necessary tools for operation (such as graspers, scissors, and clip-appliers), is inserted into the abdomen through some openings with a diameter of five to ten millimetre. The images of the internal organs are transmitted via the laparoscope to an external video monitor and allow the surgeon to make a diagnosis as well as to perform the surgery using the inserted tools (see figure 3).

³ Source: <http://emedicine.medscape.com/article/453705-overview>

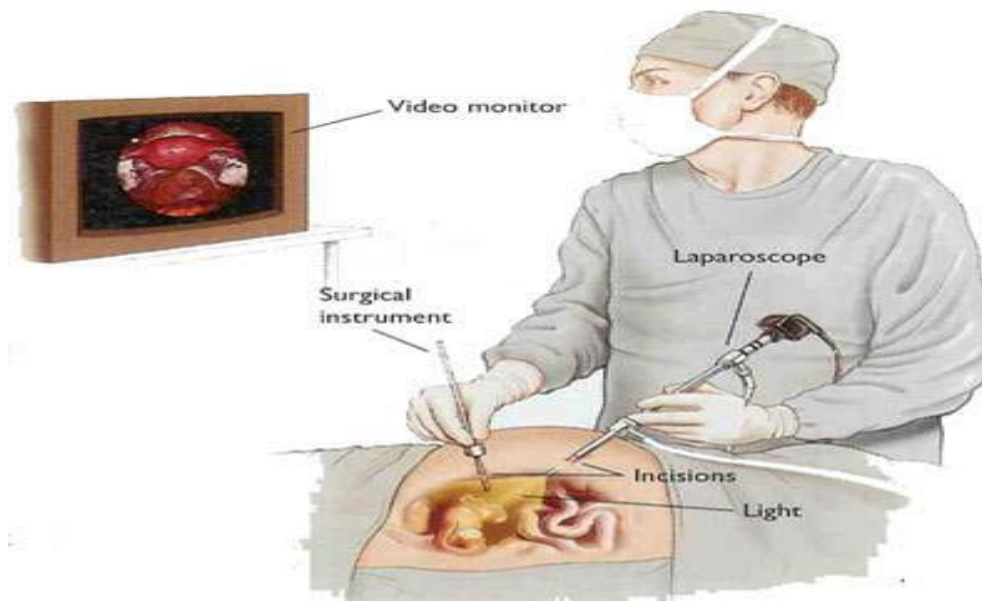


Figure 3: Scheme of laparoscopic surgery (Source: www.rfay.com.au)

Laparoscopic surgery is typically a minimally invasive surgery (MIS) because it is less invasive than open surgery for the same purpose. It requires a smaller incision to reach the target inside the body. A minimally invasive surgical procedure is therefore an operation within the abdominal or pelvic cavity that involves the use of a laparoscope. Laparoscopic surgery has been adopted by various surgical specialties, including gastrointestinal surgery, gynaecology and urology.

The general advantages of minimally invasive (laparoscopic) prostatectomy (LRP) versus open surgery are considered to be a smaller chance of bleeding and infection, fewer post-operative complications, smaller incisions (better cosmetic results, less pain and less scarring), a faster recovery and shorter hospitalisation.

In the field of urology, enthusiasm for laparoscopic surgery became noticeable since the 1990s during which it evolved from being a merely diagnostic device to a device with surgical capabilities. Later on, the use of laparoscopic surgery was extended to comprise the entire removal of a cancerous prostate.

Robot-assisted radical prostatectomy (RARP)

RARP is one of the latest methods of prostate surgery and is the main focus of this study. It is a new minimally invasive surgical procedure with the mediation of a laparoscopic device (robot).

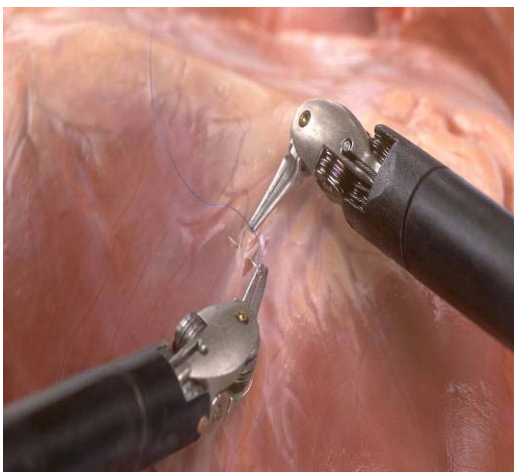
The first working robot is accredited to Leonardo da Vinci in 1495 and the breakthrough of robots came in the 1970s, in the car-manufacturing industry (EAU conference webcast 2009). The concept of robotic surgery was initially the product

of military interest within the American army. The intention was to provide remote medical care while keeping trained doctors safely away from the battle field. In the early development of surgical robots in the US, surgeons affiliated with the US army often played an important role as advisors or chief commissioners in communicating with industrial manufacturers (Middelbeek 2007). Some years later, a robotic surgical system called the da Vinci® system was developed and produced on a commercial scale by an American firm called Intuitive Surgical Inc. It was approved by the FDA in 2000, received CE marking in the same year, and became fully accredited in Europe (Camberlin et al. 2009, Llanos 2006).

The proliferation of the da Vinci surgical system attracted the interest of urologists as well as patients, and led to a sharp increase in its diffusion. Among other surgical specialties, the urologists are considered as relatively late but quick adopters of RARP (Middelbeek 2007). RARP is now the most common surgical technique for removing a cancerous prostate in the US (Ghavamian 2009) and the most common surgery with the use of a robot worldwide (Murphy et al. 2008). According to the manufacturer, the worldwide installed base of the da Vinci surgical system exceeded a thousand in 2008 (Camberlin et al. 2009).

Description of the da Vinci robotic system

The da Vinci surgical system consists of four electro-mechanic robotic arms placed at the operating table. One robotic arm provides lights and a camera, and the rest move surgical devices inside the patient. The surgeon is seated at a console distant to the operating table and controls the movements of the robotic arms remotely with handles. At the same time, a three-dimensional high-resolution panoramic image of the operative field, i.e. inside the abdomen, is provided at the console. Thereby, the surgeon no longer needs to stand at the operating table (figures 4-7). According to the manufacturer, the da Vinci surgical system is a remarkable technical improvement over conventional laparoscopy, in which the surgeon operates while standing, using hand-held and long-shafted instruments without wrists.



Figures 4-7: Robot-assisted surgery; the surgeon's console, robotic arms, handles and surgical instruments (Source: Intuitive Surgical)

Costs of purchase, maintenance and use

Costs of purchase and maintenance vary across countries. The current costs of a da Vinci system include a purchase price of approximately 1.7 million Euros plus a maintenance cost of about ten per cent of the catalogue price per year (Camberlin et al. 2009). In 2006, it amounted to 1.2 million Euros plus a maintenance cost of about 25 per cent of the original price per year (ibid.). The cost of reposables should also be added. Reposables are instruments such as cutters, needle-holders, etc. which are inserted into the robot arms. After a predefined number of procedures — usually ten times — the reposables are electronically rejected by the system and have to be replaced with new original ones sold by the manufacturer of the da Vinci system. In Belgium, the costs of reusable materials for radical prostatectomy amount to 2870 Euros per procedure (ibid.). A Dutch hospital, which is considering the purchase of a da Vinci system, estimates in its business case the total cost (purchase, maintenance, materials, and personnel) of about one million Euros per year if the purchase price is to be set off over a period of five years.

Current status of da Vinci surgical systems in the Netherlands

As of December 2009, there are ten centres using eleven da Vinci surgical systems in the Netherlands (contact with Intuitive Surgical). At the same time, at least two other Dutch hospitals are considering purchase of the system (direct contact with the managers of those hospitals).

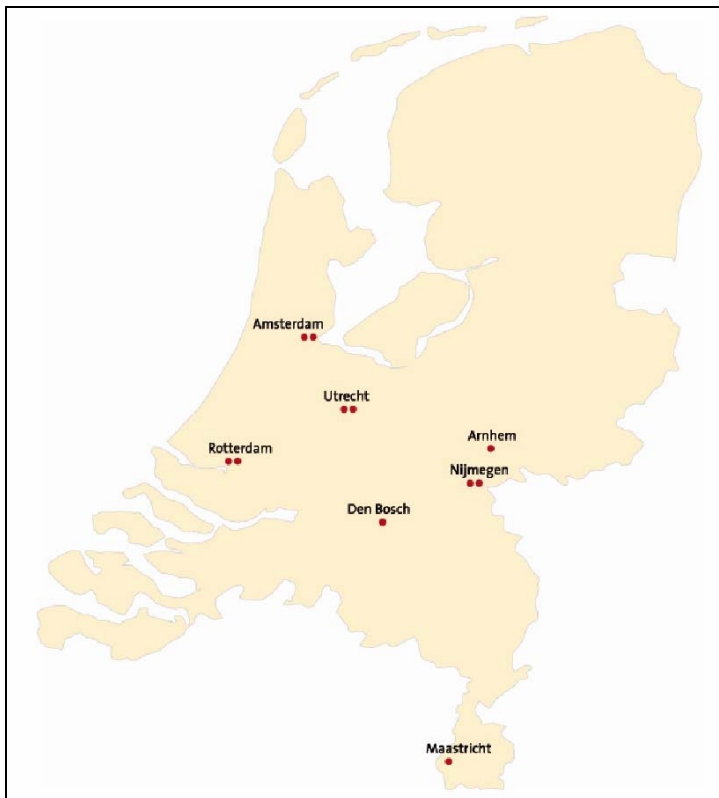


Figure 8: Installed base of da Vinci surgical systems in the Netherlands, December 2009 (●)

***Financial status of
RARP in the
Netherlands***

For readers who are not familiar with the way curative care is currently financed in the Netherlands, a general overview is given at the end of this report (annex a.). Robot-assisted prostatectomy is insured care and thus included in the benefits package. In May 2007, at the request of a private insurer, CVZ issued a positive clarification statement (*Duiding*) on the insurance status of RARP: "Laparoscopic radical prostatectomy with the help of the da Vinci robot fulfils the norm of Established Medical Science and Medical Practice (*Stand van de Wetenschap en Praktijk*) and is therefore part of the benefits package" (Request for Advice [*Adviesaanvraag*] (CVZ 2007a). RARP was recently shifted from the A-segment to the B-segment of care. This means that hospitals and insurers are free to negotiate the price to cover the (extra) costs of using the da Vinci robot. Robotic prostatectomy currently has no separate DBC code (DRG-like declaration code) and is declared via the LRP declaration code. The current tariff for the LRP code is 8,000 to 9,000 Euros and – according to one hospital – the negotiated price for RARP is around 11,000 Euros. However, that same hospital is now planning to renegotiate with the insurer for a higher price of around 12,500 Euros for RARP because (according to the urologist of that hospital) the current price (11,000 Euros) is still low. At the same time, the Dutch Association of Urology is considering a proposal to request a new declaration code for RARP (interview with a board-member of the Association).

The next part of this report describes the empirical processes by which the demand for RARP is constructed and perceived by the stakeholders.

2. THE CONSTRUCTION OF DEMAND FOR DA VINCI SURGERY

2.a. Robotic surgery as a medical innovation

The role of the government

The government is probably one of the most important stimulators of research and innovation in many countries, including the Netherlands, and in many sectors including health care. Much of this stimulation is performed via direct financial incentives such as an innovation budget or indirect subsidies for universities and research institutes. In general, many governments consider the promotion of innovations in the form of technological innovation (Middelbeek 2007). The stimulation of innovation may be a government's priority in some countries, notably the United States, where it overcomes the cost-containment role of the government with regard to total health care expenditure (ibid.). Medical-technological innovations can be a promising platform for investment. A case in point in the Netherlands is a joint initiative of a University Medical Centre (academic hospital) and a technical university for medical-technological innovations including further developing minimally-invasive surgery (MIS) with the da Vinci surgical system. So far, both universities have invested heavily in buildings and infrastructure. A five-year budget of about 180 million Euros is proposed for this project, part of which is to be funded by national governmental agencies and funds from the European Union (Hoogeveen & Burie 2009).

User involvement in development

Clinical practice is the interface of patient treatment and the development of medical knowledge and expertise. Blume's model of technological innovation in health care applies here (Blume 1992, Middelbeek 2007). According to this model, the producer-user interaction is an important determinant of the use and development of new technologies. This interaction is often in the form of a 'knowledge synergy' between the producer and the user (ibid.). 'Users' of the da Vinci robot, namely urologists and hospitals, see MIS and robotic surgery as a good platform for contributing to the production of clinical-technical science in addition to the task of treating patients. This suggests that an important factor in inducing the sense of need to use da Vinci surgery is the users' intention to participate in medical-technical knowledge production facilitated by the robot. The involvement of medical professionals in developing MIS techniques is evident in the above-mentioned initiative. "The main purpose of this platform", according to its introductory report, "is to facilitate the exchange and transfer of knowledge and expertise among the participants" (Hoogeveen and Burie 2009:7). One of the organisers of this plan, who is a medical specialist, is a respondent of this study. He describes how the enthusiasm for technological innovation has resulted in this collaborative

platform.

There was an idea in our hospital five years ago that, now that we have all new techniques (tissue engineering, computer science, and so forth), it would be wise to work in collaboration with a technical university, focusing on better treatment options in minimally invasive surgeries ... and robotics is one of them. Robotics is an innovative patient treatment with minimal invasiveness. Of course, this idea has been evolved over time. We have realised that the only way to push this area is multidisciplinary collaboration with a technical university. It is a big plan and it is the way to go.

He further mentions that this collaboration aims to enhance the quality of patient treatment and increase the productivity of the health care system in diagnosis, treatment, R&D, in innovation, in creating new business initiatives, in co-operation between academia and industry, and in training and teaching. The enthusiasm of the two medical and technical universities in developing this high-tech innovative platform further is evident, as both universities have already invested heavily in it. "Medical demands are smoothly translated into technological specifications by combining a multitude of clinical specialties and all the technological disciplines that are necessary for minimally invasive treatment" (Hoogeveen and Burie 2009: 6).

The 'coalitions of interest'

The development of a new technology such as robotic surgery underpins the interests of medical professionals to advance the clinical and scientific applications of robotic surgery on the one hand and the economic interests of the manufacturer on the other. The rapid uptake of the da Vinci system in clinical practice represents the enthusiasm for more collaboration between hospitals and the manufacturer. Although the interest of medical professionals and the manufacturer may be different in nature, they serve mutual benefits in the development of technology and are therefore *symbiotic*. Through coalitions of interest, both the medical and the commercial position of robotic technology are consolidated towards a certain direction that satisfies both parties. Coalitions of interest direct technological innovations toward the maintenance of expertise, prestige, income and competition (Blume 1992), resulting in an enhanced sense of need to adopt this new technology.

The da Vinci system is, therefore, an instance of a "technological zone", as described by Faulkner (2009), in which the industry and the innovation networks come together within a certain political economic structure that fuels their 'strategic alliance' towards furthering technological innovations in health care.

***The American
context of
emergence***

Intuitive Surgical, the only current manufacturer of the da Vinci system, is an American firm. It is important to realise that the creation of the image of the da Vinci surgery and subsequently the perception of demand for the device reflects the particular social context and health care system of the United States, in which the da Vinci system originated and was initially promoted. “Robotic-assisted surgery”, Intuitive Surgical quotes a urologist, “is safe and effective and is a new reality for American surgery”. But what does this mean with respect to the construction of need for RARP in the Netherlands?

For many years the United States has had an important forerunner’s role in stimulating and ‘valorising’ innovations in the form of technological progress (Middelbeek 2007). At least at a micro-level, this way of conceptualising technological innovations has been reproduced and spread thanks to the many connections between the American robotic centres/surgeons and their enthusiastic colleagues as potential adopters all around the world. According to urologists in this study, the US is now a favoured destination for many (Dutch) urologists seeking training in robotic surgery. Upon returning to their own country, they are quite likely to promote the da Vinci system and influence local colleagues.

Studying some virtual forums of patients with prostate cancer shows that in some countries, including the United States and Australia, patients often hesitate to choose RARP because of its high out-of-pocket expenses or due to possible financial consequences for their private insurance policy. It is no surprise that, within this context, more intense publicity is needed, in the form of both professional and direct-to-consumer information, to be able to convince more patients to undertake RARP and more hospitals to purchase it. In countries with a different health care system — such as the Netherlands, where a third party pays almost all operation expenses via the social health insurance — there is no such barrier. Yet global communication channels such as international virtual meetings, congresses, and so on, continue to seek out such publicity and transmit it from the land of origin (the US) to the rest of the world. The end result is that the intensely commercialised publicity, originated within the American socio-economic context, is able to induce the demand in the Netherlands. A Dutch urologist expressed surprise at seeing ‘a very big billboard with the first robotic surgical team on a highway in the US’. “That’s how they advertise” he says.



Figure 9: Two robotic surgery advertisements on billboards in the US (Sources: www.marshallastor.com/ and www.boston.com/)

Another instance in which country-specific differences are addressed is the debate about prostate cancer screening. Two urologists and a board-member of the prostate cancer patients' organisation discuss how the screening for prostate cancer in the United States has influenced the demonstrated effectiveness of the da Vinci robot.

America is the place where beautiful stories about da Vinci robot come from. Men are screened in America, and prostate cancer is often detected in men of 45 years of age ... i.e., at an early stage, with a lot of T1's, a small tumour, and inside the prostate. Naturally, those operated in an early stage by the robot have had very good results [surgical outcome]. But there are also a lot of people in that group that perhaps didn't need the treatment, because they wouldn't have got problems in the future anyway. In the Netherlands, we now have a discussion about "screening", along with all the pros and cons. We will be just like the Americans if we also make the robot too lucrative (board-member of the prostate cancer patients' organisation; also re-stated by two urologists).

2.b. Da Vinci surgery as a point of attraction

The attractiveness of the da Vinci system is examined in a number of domains: technological progress, nomenclature, compatibility with the field of urology, newness, and the increased involvement of medical staff in the operative field. These domains are described in more detail below.

A high-tech platform

The introduction of a new technological device often produces a reaction of 'wonder', due to advances in technology (Blume 1992). This reaction stimulates curiosity and the interest of many potential users to consider involvement with the new device and the possibility of developing it further. Moreover, the technological advance of the da Vinci robot depicts a high reputation image of da Vinci surgery. The curiosity of individuals, as well as the high profile image of the device, can be important in the drive for demand. In as far as high-tech care is regarded as high quality care, the technological advance presented by the da Vinci robot and its subsequent sophistication is regarded as providing the best possible care, thereby allowing next to no doubts about demanding it.

"The precision and flexibility of this type of computerised system will allow us to do things we haven't even thought of yet"; "...The promise of technology really seems to come true"; "It appears to be the apex of technology". These are some typical arguments taken from the Intuitive Surgical website, quoting patients and urologists. These indicate that the technological advance brought by the da Vinci system forms the backbone of the promotional messages conveyed by the manufacturer. The manufacturer's website appears with a motto in its homepage, saying: "Taking surgery beyond the limits of the human hand" (figure 10). The same message is also conveyed in scientific discourses, for instance, in a number of presentations in the 2009 EUA conference webcast.



Figure 10: The logo of the Intuitive Surgical taken from the homepage of its website

A respondent, who is director of the medical technology division of an academic medical centre, argues:

When patients choose to go to an academic hospital, they know that there are a lot of new devices there. They know that, even though you are very ill, in the academic world, every ten minutes a co-assistant comes and asks the same stupid questions. They know that the urologists in peripheral hospitals may be as good as or even better than the urologists in academic hospitals. They probably come here for the new technology ... Patients hear nice stories about new technologies. Otherwise, they would have gone to a more classic hospital.

The nomenclature of the 'robot'

The smart nomenclature of this surgical device also plays an important role in inducing a perception of perfection among the stakeholders. None of the respondents in this study disagree with the influence of the very words 'robot' and 'da Vinci' to name a remotely-controlled computer-assisted, minimally invasive device. One RARP patient, who is a technical engineer, argues:

It's like the doctor is drinking coffee and the robot does the work [sarcastic tone]. The word 'robot' means that it does something on its own, but it does not do anything on its own. It's just an instrument. The word 'robot', of course, sounds **magical**. The word robot suggests that things can't go wrong anymore. And 'da Vinci' is entirely a beautiful word. Such a sublime set of words were chosen for it.

A robotic urologist gave a presentation on RARP in the 2009 EUA conference in Stockholm. He described the origin of the concept of robotics and robotic surgery by showing the following image to the audiences. "Robots", he says, "don't go on strike, robots you don't need to feed them; robots are [there] 24 hours a day, 7 days a week; they work more precisely than humans; they can do the same exercise over and over again ..." (EAU conference webcast 2009).

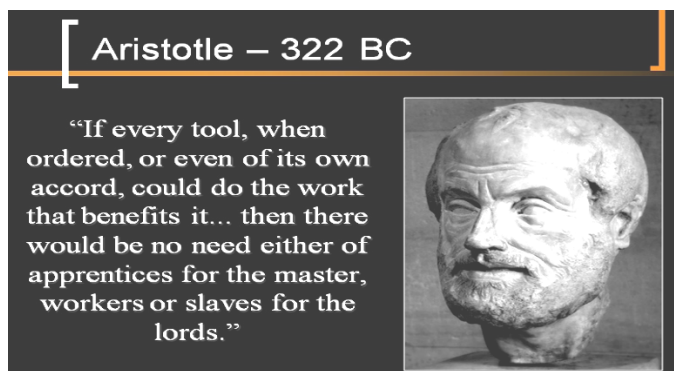


Figure 11: Taken from a Powerpoint presentation by a robotic urologist in the 2009 EAU conference

In her weblog, 'Living with Prostate Cancer', a "savvy prostate cancer reader, writer and spouse" describes:

About six months ago I heard a commercial on the radio about a state-of-the-art treatment for prostate cancer called "Cyberknife." It was being offered at a hospital in a suburb of New York that I had never heard of ... Well, my mind became immediately erect! But my gut reaction was negative: concern, even fear ... that folks in the PC [prostate cancer] community were going to **fall for it** in a big way, regardless of its merits. That's because anything health care-related that has the word "cyber" in it is "sexy" these days. Same for "robot". If you're a clever marketer, you're going to find a way to slip those words into your promotional materials (<http://prostatecancerblog.net>).

'Compatibility' with the field of urology

Urology lies at the intersection of clinical practice, medical science, surgical procedure and technological devices. Compared to other specialty fields, the field of urology has a strategic position in the construction of the need to use robotic procedures.

In the field of urology you have the whole package of research, patient contact and surgery all together. That's one of the reasons why they chose to become a urologist in the first place (interview with operation theatre nurse).

As mentioned before, urologists played a limited role in the initial development of da Vinci surgery and were late adopters. However, they gradually became one of the most important specialists to use and develop da Vinci surgery. The integration of urological clinical science and technological developments has made the field of urology a technologically-oriented specialty and compatible with the integration of this new method (Middelbeek 2007). In particular, whereas the initial developers of da Vinci surgery, such as neurosurgeons, did not have prior experience, the field of urology did have the privilege of such experience, in the form of the usual laparoscopy. At the same time, the da Vinci robot emerged in a context where the popularity of MIS in urology continued to grow tremendously, among both patients and professionals. Furthermore, operating on the prostate is seen as an ideal operation with da Vinci robot because "it helps you to operate in a very small difficult-to-reach area" as one RARP urologist puts it. Therefore, the compatibility of robotic surgery with the field of urology and prostate surgery makes robot surgery a rapidly-diffusing surgical procedure in this field and contributes to a great extent to the sense of need for it.

***The circulation of
knowledge
surrounding
robotic surgery***

The second reason for a rapid adoption of robotic surgery in urology is a significant growth in scientific publications about robotics in urological journals (Middelbeek 2007). From 2000 onwards, urologists' interest in publishing early experiences with the robot has caused an exponential increase in the number of scientific publications on this topic. This was also associated with the proliferation of more specialised 'new' journals such as Journal of Robotic Surgery sponsored by Intuitive Surgical (since 2007) and the International Journal of Medical Robotics and Computer-Assisted Surgery (since 2004) (Middelbeek 2007).

Parallel to the emergence of new scientific journals, organisations providing medical communication and education also play an important role in circulating the latest knowledge and expertise among professionals. There are many congresses, seminars and educational sessions organised by congress organisers or medical research centres and quite often sponsored (partly) by the manufacturer. One example is a Master Class in Robotic Prostatectomy, with an international scientific board, which started in 2009 with an affordable fee (about 250 Euros in Belgium). Another example is the 2009 EAU congress. RARP was an important topic at the annual EAU congress in both the EAU-endorsed scientific meetings and the adjacent exhibition programme (marketplace/commercial programme). Organising scientific meetings about robotic surgery has become an unalterable aspect of the congress agenda, and one that is facilitated by manufacturer sponsorship. In the 2009 EAU congress Intuitive Surgical was present as a 'Gold Corporate Sponsor'. This sponsorship involves the provision of an unrestricted educational grant that requires the congress to focus on the topic of robot surgery (in particular, issues identified by the scientific board of EAU congress). A member of the Sales & Marketing Department of EAU congresses states:

... besides the scientific meetings [approved by the board of the congress], there was also live surgery with da Vinci, organised by Intuitive Surgical, in the exhibition part of the congress. It was extremely popular. The urologists in attendance were extremely excited. The outcome of this live surgery session is more promotion. It was held in a separate room from the congress room ... and the company presented it in a very professional way.

The intense circulation of knowledge is partly due to the urgent need for evidence of effectiveness and partly due to the reputational interest of urologists/hospitals to reflect on their work in international journals/congresses in relation to their (organisation) research career or personal status (Middelbeek 2007). In this way, a large 'reputational structure' (Blume 1992) with international journals and congresses has been

established around robotic technology. In this way it can bear witness to potential users of the da Vinci robot and speed up its adoption.

The ergonomics of da Vinci surgery

It seems reasonable that da Vinci surgery provides a better ergonomic position for the surgeon because (s)he is in a more comfortable position (sitting at console while operating) than LRP or ORP. Ergonomic concern can be an important incentive for many urologists and particularly for those who perform usual laparoscopy to consider switching to da Vinci surgery.

The usual laparoscopy has been performed in the Netherlands for about two decades.. Laparoscopic surgeons are mainly in their 40's/50; s. Due to the ergonomic advantage of the RALP, a number of laparoscopic surgeons have started to think about switching to the robot because they fear they may not be able to continue a long career with usual laparoscopy. The sooner you switch to the robot, the fewer ergonomic consequences of usual laparoscopy, there will be for you and the less the possibility of having to quit your job because of neck or back arthrosis. Surgeons are often unable to enjoy their retirement because they either die or get sick early due to the work/physical stress they have had [during years of operation]. A colleague of mine, who has neck arthrosis after some years of laparoscopic surgery, is now happy to work with RALP [and this is confirmed by that very colleague in a separate interview].

The newness of the surgical procedure

Another attraction of the robot is its very newness. Since the da Vinci system is a new surgical method for prostate cancer, it is considered as the best option. This can be referred to as the newer-must-be-better mindset. To that end, the very existence of the latest technology tempts hospitals to purchase it, doctors to operate with it, and patients to be operated with it.

The fact that state-of-the-art technology is an important drive to demand a device is not exclusive to RARP. This seems evident in many other areas of life as well:

...you see things are changing and everybody wants the newest, fastest car and everybody wants a high-tech robot because they want to be 'modern' and think that is better. Some people are attracted by the fact that it is a robot, a high-tech surgical procedure, but for the same reason some people choose a new car with too many new technical accessories and a complex stereo or a mobile phone with all sorts of gadgets, whilst others may say that they mainly want to make a phone call with their mobile phone (theatre nurse).

Some respondents believe that the pursuit of the latest is a global trend, but it can also be seen as “typically Dutch” or as “part of Dutch culture”. A DBC-O official, among others, describes:

...it has to do with our norms and values. It is part of our genetics [culture/mentality]. It is a typical characteristic of us, Dutch people, including doctors and patients. We want every new thing as soon as it comes into existence, no matter how useful it is for us and no matter how much it costs and who has to pay for it. I would call this an ethical problem on a macro-level [collective level]. There seems no end to this process, though it has to stop somewhere.

One urologist also points out:

...people want to be operated using the newest technology and the robot is the newest so that **must** be the best. That’s a very important reason to buy [demand for] things, though it is difficult to quantify in money or in a better operation outcome ... If you hadn’t heard about the robot, you would have just gone to the nearest hospital and got the prostate operation done there.

This cultural process seems a general belief that applies to many parties in the field, including urologists, patients, insurers and the media. For instance, as the board-member of the prostate cancer patients’ organisation says, “when urologists hear about da Vinci prostatectomy at a scientific congress, or from the literature, and promotions, they quickly think about having [getting hold of] it”. In the era of free flow of information, it is not a difficult task to raise awareness about the existence of everything that is new. Most promotions simply work in this way.

Involvement with operation

Compared with the other two methods, the da Vinci system facilitates a more direct engagement of the theatre nurse and the surgeon’s assistants with the operative field. In a sense, the robotic surgeon’s reduced direct engagement in the operation is compensated by the increased engagement of the theatre nurse. Interestingly, while the surgeons are happy with reduced engagement, the theatre nurses are happy to have more of it. This resonates with the overall enthusiasm in using or demanding RARP. A theatre nurse describes it further:

As theatre nurses we used to do the clipping and suction with the usual laparoscopy. Now we do more because the robotic surgeon usually does not come out of his console to do the sutures and theatre assistants do that. Thus, for us it is fantastic that we do a bit of the surgery. For us it is ‘the cherry on the cake’. With laparoscopic surgery you stood at the operating table and sometimes it was boring.

2.c. Minimally invasive surgery as ‘the future’

In this section the move toward MIS in urology and its associated need for RARP as a new MIS method is described. There is almost no doubt among urologists in this study that MIS is the direction toward which the field of urology is moving. Being essentially a laparoscopic method, the da Vinci robot is a step towards the future as “a perfect interface to transition” from ORP to MIS (Ghavamian 2009: 864). The increasing popularity of MIS goes hand-in-hand with the perception that the MIS method is ‘the way to the future’. This is shared by many respondents in this study, including urologists. A urologist, who himself operates prostate using the open method, describes it decisively:

Times have changed. Years ago, a surgeon had to have a knife to be able to operate, but nowadays, under the current *Zeitgeist* [the spirit of the time], the philosophy of urologic operation involves minimally-invasive laparoscopic techniques. The era of open surgery in urology is over. MIS is becoming the mainstream. The countdown has already started and open surgery will have to be abandoned. In the near future an increasing number of operation rooms will be [mainly] filled with robotic arms [without the presence of a surgeon]. This is the upcoming scenario ... Do you remember the large scars on patients’ bodies? That’s all in the past. Forget they ever existed.

...The prostate **belongs** to the robot. It has already been decided worldwide. In as far as hospitals can afford a robot, the prostate belongs to the robot and there is no further discussion... Laparoscopic surgery is becoming standard in [clinical] practice. You can see that from the growing body of evidence. Of course, there is some resistance and hesitation, but that is due to a political cause. Older urologists, who are often powerful in their field, have got used to open surgery. They are no longer able to learn new techniques or they may be afraid of complications.

The move toward MIS, initiated with the use of usual laparoscopy about two decades ago, has been considerably accelerated by the da Vinci system. The recent widespread movement toward MIS has been reported in the literature (Descazeaud et al. 2007). The perception of MIS as the future creates a strong incentive for a growing number of urologists (and hospitals) to consider switching to da Vinci surgery, because in fact, this is the latest MIS method. “You see that the emergence of RARP is the [next] logical step in the innovation process after usual laparoscopy”, is how one MIS urologist put it, with a strong emphasis on the word ‘logical’.

The move towards MIS is driving, not only practicing urologists but also future generation of urologists, i.e., residents, to

direct their professional career towards the da Vinci system. The learning environment in MIS training (including that of robotic surgery) is also shifting from learning by doing to learning by 'simulated reality' (Hoogeveen & Burie 2009). This provides an increasing number of potential surgeons with the possibility of learning MIS. On the other hand, MIS urologists say that they no longer teach residents the conventional method of prostate operation. "Once it's emerged you won't go back again [to the older classical method]", "We do not perform open surgery on prostates, adrenals, and kidneys at this [academic] hospital and I do not teach my residents open surgery any longer". These are some typical quotes of MIS urologists in this study. Practically, this process seems irreversible to the extent of posing this question in the literature: "[W]ill the new generation of urologists be able to perform radical prostatectomy without the robot?" (Descazeaud et al. 2007:11).⁴

2.d. Performing 'better than the competition'

This section describes how competition incentives within the context of care delivery can contribute to the construction of need for the da Vinci system.

Image-building

Within the context of a market-oriented health care system, care-providers and insurers are allowed to compete for profit in order to increase efficiency. The da Vinci robot is considered a technologically superior MIS procedure and capable of offering high-quality care. It may be portrayed as a sign of clinical excellence, medical expertise and innovative surgery. These prospects may then be used in the competition game. The da Vinci robot enables hospitals and insurers to attract more clients, urologists to increase their professional profile and get hired by prestigious hospitals and allows patients to - at least - 'feel' better. The da Vinci robot provides a ground for and mediates competition between stakeholders in care delivery. "It's like buying a luxury car to let your neighbours know that you can afford it", a robotic surgeon says! A da Vinci operation assistant and (also) a member of the hospital's policy committee describes her hospital's policy and the 'ambition' to operationalise 'good entrepreneurship in health care' with the use of robot. Her analogy with a football match is particularly notable.

Before the robot, we used the open method for prostatectomy in our hospital. We have recently started using the robot. All radical prostatectomies have been done [exclusively] by the robot since then,

⁴ Expertise to do open surgery is necessary for robotic surgeons because they may need to convert to open method emergently, for instance, in the case of life-threatening bleeding during RARP (Blute 2008).

because we need to make a 'name' with robot and we use the robot as a promotion to make the name of our hospital familiar ... We are very active in promoting ourselves, from promoting the shops we have in the hospital to the robot we operate with. ... Once you have bought a robot, you have to put it in the centre and say that you have it; then you make commercials; you make reports for newspapers and magazines; you communicate with GPs that if they have these kinds of patients, they can send them to you because you have high-tech health-care. ... You commercialize yourself, let everyone know that you have medical expertise because you use the robot. The medical centre near to us have purchased the robot but they don't use it and it's collecting dust [!]; they would miss the votes; we are now using the robot and people as well as GPs hear about that and they refer patients to us. The idea behind promotion is to have a reasonable percentage of the market share in 2012. I also have to add that our hospital used to have a religious identity [which attracted patients accordingly]. Nowadays, there is no religious identity anymore and there are lots of hospitals in the region. So we have to promote ourselves to attract patients. ... But if the other hospital in the region were also to purchase the robot, they would never benefit financially as much as we have done because they would be too late; we have already built a name in robot surgery in this region. It's just good entrepreneurship, as long as making profit is allowed by the government...

...

As a hospital we want to show Minister Klink [Dutch Minister of Health] that we want to make profit in health care together with lobbying with the NZa. We are really very market-oriented now and we want to be a top hospital. ... The robot helps to promote our name in the region and shows that we are good. We have the ambition to go for profit. ... It's like the football league. We want to be the 'Ronaldo' in the world of hospitals. If we cannot compete in the champions' league, within our budget and with the types of procedures we can do [by government's decision of not licensing certain procedures], we want to be at least *FC Twente* or *Feyenoord* and compete with European [football] teams. ... Of course, not all hospitals have the ambition to fight for the top position.

And the same process seems evident in insurers' decisions to purchase care and contract hospitals. Insurers are asked why they are willing to contract RARP with hospitals and pay extra money to them.

Hospitals want to deliver the [new] care, and then they come to us for a contract. It also creates a good image for our company ... that we are buying the best care delivered by the best doctors in an excellent urologic centre in the Netherlands. ... We can say to the media — and we have already said to the press — that we have contracted this new care (medical advisor of an insurance company).

The process of image-building as such contributes to the perception of the need for RARP within the context of care delivery. The da Vinci robot can trigger competition at different levels: among urologists, between hospitals, or even between cities, regions, or countries. For instance, a number of robotic centres in Belgium and Germany try to attract Dutch patients, especially those living near the borders. “There are more and more hospitals like hospital X that think: if we don’t have a robot, we cannot keep up in the field”, said the board-member of the prostate cancer patients’ organisation. “Once this process has started in one insurance company or hospital, others soon start as well and it is difficult to stop this process”, a care-purchaser of an insurance company confirms.

Differentiation

The purchase of the da Vinci system offers hospitals a better position in the competition game. Once the da Vinci system has been implemented, a hospital is able to differentiate itself from other hospitals and enjoys a more privileged competitive position. This prospect of differentiation plays a large part in constructing the sense of need to purchase RARP. A da Vinci urologist and the theatre nurse describe it respectively:

...7 years ago the field of urology was at the bottom of the list of operations with a robot. There is a political reason for the rapid diffusion of RARP among urologists. In the US there are two divisions of urologists: cancer surgeons and endo-urologists (minimally-invasive urologists). With the emergence of laparoscopy, the latter took patients away from the former. Moreover, cancer surgeons had no chance to master the technology. Then RARP emerged. Using robots, the oncological surgeons could then take patients back from the endo-urologists, while finding a good chance to master the technology as well. ... Of course, this is where the story originated, and here [in the Netherlands] competition between hospitals is more important.

...

... We [the neighbouring hospitals and ours] have been fishing in the same pool, which is our city. But now that the robot has emerged, the details are becoming important. ... We don’t want to be just a general hospital, of which there are so many in this region. ... I think that, in the end, competition causes the

differentiation of hospitals.

The process of differentiation may result in a tendency for robotic surgery to be conceptualised as a sub-specialty field (of urology).⁵ Two respondents clarify it:

... There was an open vacancy for a urologist. Dr. X applied; but he would only come to our hospital if we purchased the robot. However, the idea of purchasing the robot came from the urologist who was already working in our hospital and he was close to the board [in the organisational tree] because he was medical staff and could probably lobby well with the board. He said, "We can hire a 'normal' urologist but we have already three of them [including him]; It's better to have a specialised urologist here" (operation theatre nurse).

...

The field of urology has changed compared with one or two decades ago. Before, every urologist did every operation. Now we are in the middle of a differentiation process. It is the current policy of the Dutch Association of Urology (NvU) to encourage differentiation between urologists in order to improve outcomes and create more opportunities for education. ... Of course, there are also incentives for competition among individual doctors for such differentiation (member of the board of NvU).

The perception of 'pressure'

The idea of commercialised publicity is not shared by all parties. Some respondents prefer not to publicise themselves or believe that promotion as such is not necessary. This is the opinion of a board-member of a hospital:

It's not the intention of our hospitals to advertise. We are not very good in public relations and I think that our doctors also believe that it's not necessary to publicize themselves in this way. They prefer to do their job well. Then, the patients will come because we use the best technology and provide them with the best care from experienced surgeons.

This is also confirmed by the manager of a da Vinci platform of another hospital:

If you want to inform the public [body language 'advertise'] about how good your hospital is and how wonderful it is to have the device in this area, you should do it via patients' groups. When you have the data from [empirical] studies to support that in your hospital, you have implemented the da Vinci successfully.

⁵ At the moment, Dutch urologists require no formal licence to perform prostate surgery with the robot.

It is not the intention of this study to compare different ideas about publicity in care delivery. The above quotes have been inserted here (in comparison with the analogy to a football match) in order to highlight the distinction between having the choice of adopting RARP as opposed to the pressure to do so. Performing publicity with the da Vinci robot renders to some extent a kind of 'choice' that a hospital or an insurer is somehow free to make or not, in order to attract clients. In contrast to this apparent choice, there are also some forms of 'pressure' to implement RARP reported by urologists, hospital managers and insurers. These pressures seem to be the 'by-products' of competition. They are perceived with less degree of freedom of choice after taking part in the competition game. These pressures can impress upon stakeholders that, at least at a cognitive level, using the da Vinci robot is a 'must-do'. "The reason [body language: the only reason] why I don't have a robot is that I cannot afford it at the moment" says a highly-experienced laparoscopic urologist with years of experience and a good reputation in usual laparoscopy. Pressure is perceived not only by providers but also by insurers. It is described in more detail below.

Pressure to provide the care

Right after the emergence of a new form of care, hospitals may feel they are under pressure to deliver that care, as is the case with insurers who are under pressure to contract that care for the hospitals. The chairman of the board of a hospital describes it thus:

What you see is that when the other hospital in the region has the robot and we have the usual laparoscopy, patients tend to think that the robot is better. The other hospital says to patients: "you should come to us because we have the robot", whilst we say: "you should come to us because we have good surgeons". But what does the public believe? They believe that you [the hospital] must have the robot, otherwise you are not good enough. That's marketing and marketing has become an element of the hospital business. At the same time, this [the new technology] is necessary in order to attract good surgeons. They say 'I'm a good surgeon and I want to work with the robot'. That's always the pressure on the system.

"These pressures", says an insurance advisor, "come from the fact that patients know about the existence of this new technique; if it's not available they go abroad; they have been informed considerably by the media, the internet, or by patients' organisations, etc.; they might -take a case to court otherwise; these are the pressures we have. ... This period [the early phase after introduction] is very difficult because the therapy exists but there is little evidence. And providers compete with one another and are under pressure".

The pressure of provision was also pointed out at the very beginning of discussion with two urologists who work near the Dutch border with Belgium and Germany:

Since I work near the border, I have experienced the pressure that patients go to Germany or Belgium. I do not have the robot at the moment and I am **desperate**. I wish I had it. Although it is commercially driven, I am forced to operate with the robot. ... There is also a local medical information service that advises and helps Dutch patients who want to have their robot-assisted operation in Germany.

...

They try to attract many Dutch patients. In fact, any Dutch patient who is operated on in Belgium is 'pure cash' for Belgian hospitals, taking into account that they usually count on local patients in their estimate of the number of procedures and the costs of purchasing a device.

Another instance of the pressure for provision is the 'use-it-or-lose-it' pressure. Notice the following discussion with a manager of a medical technology department in an academic hospital which recently purchased the robot:

[Interviewer:] How did you come to the decision to purchase the da Vinci system?

[Respondent:] The non-political reason is that it's just a joystick. ...The prostate is hard to get at. With the da Vinci robot, you can go to the target tissue (prostate) more easily and operate with less damage to surrounding tissues. You cannot turn your wrist 360 degrees but the robot can. So it is more precise. ...

[Interviewer:] And what was the political reason in your opinion?

[Respondent:] Well, politics always plays a role. All academic hospitals have the robot and we should have one. It makes sense in this way. Otherwise, colleagues from other centres would ask you: "Don't you have the da Vinci [ironically]? You lose it".

Pressure to contract the care

In spite of the fact that insurers are allowed to make arrangements (selective contracting with regard to purchase, price and patient referral), it seems that in practice insurers have no option. "When too many patients and doctors want it", says a da Vinci urologist, "I think that [Dutch] health insurers also have to follow the market and pay for it. This is the case in many countries and not only in the Netherlands". A medical advisor of the Sector Organisation of Private Insurers (ZN) — and also care-purchaser of an insurance company — explains it further:

There is in fact no real negotiation between hospitals and insurers. Insurers have to buy all DBCs for all

hospitals. They have no choice. You may say that for academic hospitals that's ok. But we cannot ask for selective contracting because we, among insurers, have competition and this is not an advantage of competition. It has not been yet possible to put limitations on patients' choices in this way. In the Netherlands no one welcomes such a limitation in their choice.

An advisor of another insurance company confirms the pressure to contract care. He also highlights the role of urologists and the impact of CVZ's decision in the perception of this pressure.

We expected patients to prefer robot surgery more because urologists say that "it is better and we cannot do without the robot", and CVZ says that it is part of the benefits package. We then have to pay for it. We have thought about making a contract with a limited number of hospitals. But we have seen that more and more hospitals want to have robot surgery. You cannot stop this process. ... At the same time, CVZ has also issued a positive statement on robot prostatectomy and we cannot say to hospitals that we are not going to contract this care. After all, if the patient goes abroad and does robotic surgery there, we still have to pay for it. Thus, we cannot refuse to take out a contract with anyone.

From the perceived pressure to the perceived need

In as far as the new therapy provides opportunities to perform better than the competition, the perception of competition-driven pressures is translated into the sense of need for RARP. Accordingly, the demand for RARP increases within the context of care delivery.

2.e. Arriving at the robotic operation

This section explains the trajectory whereby a typical prospective patient with prostate cancer comes to undergo an operation with the robot rather than one of the other treatment alternatives.

"The cancer must go away"

Let us examine the patient's choice of robot surgery step by step. The journey may start from the very first moment that the patient is diagnosed and labelled as having prostate cancer. Like many other cancers, the patient's main concern at this point is to find a therapy that 'eradicates' the cancer totally. Surgical treatment seems more consistent with the patient's urgent concern that the cancer should entirely go away because the cancerous prostate is removed radically from the body. This is probably the main reason why prostate

surgery is preferred over non-surgical treatments methods.

The decision was whether to operate or to have chemotherapy. ... If you've got cancer, you just want to get rid of it as soon as possible and if you operate, you will get rid of it (patient 1 in annex c.).



Figure 12: A da Vinci ad. (Source: <http://www.orlive.com/davinci/channels/davinci-urology>)

'No way to wait'

Prostate cancer is usually a slow-growing tumour. According to guidelines, an ideal candidate for RARP is a relatively young patient with a truly localised low-grade tumour. However, it is possible for the same cluster of patients to consider the method of 'watchful waiting'. This method involves regular monitoring of the growth of tumour with clinical and laboratory tests, without doing any procedure. Obviously, this method is non-invasive and ironically it is less invasive than minimally invasive surgery. While minimal-invasiveness is highly valued over invasive (open) surgery, non-invasiveness is not valued. It receives little popularity because it is very often regarded as 'doing nothing'. If the patient with early stage cancer struggles between these two options, it is more likely that the RARP will be his final choice. As the board-member of the prostate cancer patients' association explains:

Cancer is cancer and the cancer must be got rid of (*de kanker moet weg*). If I need an operation, the next day is better than in two days' time. Because the longer you wait, the more nervous you will be.

...

It's difficult to explain to people that 'watchful waiting' is a good option and many patients refuse to accept it. I know from our association that, if the doctor says: "Sir, you can wait and do nothing for a year, just come every three months for a check-up and monitoring", a lot of people think: "He just wants to get rid of me; he thinks I'm not important or I'm not rich enough, etc."

This is how they see it, though in fact it's a very good option.

The availability of information

In the information era, citizens are often overwhelmed by the huge amount of information available on the internet about almost everything. A simple non-specialised search for prostate operation using a common search engine is likely to lead patients to a variety of quasi-scientific and tailor-made information about da Vinci surgery (see also figure 13). It is beyond the scope of this article to analyse on-line information about da Vinci surgery. However, it is plausible to assume that some stakeholders have more means and a strong motive to 'produce' such information. Promotion by the manufacturer as well as the competitive climate within hospitals are the main factors contributing to the spread of the articulated risk of prostate cancer and its new treatments via the internet, thereby increasing general awareness about RARP and inducing demand. The information depicting the promising image of the da Vinci system is presumably pervasive and easier to find than more conventional surgeries, and than possible negative stories about da Vinci.

When you, as an ordinary person, google using the keywords 'robot' or 'da Vinci' for prostate cancer, you get a lot of information. There are a lot of stories from the da Vinci manufacturer plus stories of the hospitals in Belgium, and also from Holland. I'm not sure if all of this information is objective. ... (interview with a patient).

...

You see that hospital X [the neighbouring hospital that purchased the robot] 'pulls' patients by disseminating information about the robot. By patients, I mean all patients who have been diagnosed with prostate cancer and want to make a choice from among the various treatment options. ... (a hospital manager).

The screenshot shows a Google search for the term "prostaatanker". The search bar contains the text "prostaatanker" and the search button is visible. Below the search bar, there are several search results. The first result is from Wikipedia, titled "Prostaatanker - Wikipedia". Other results include "Prostaat.nl - Alles over de prostaat" and "Prostaat.nl - Prostaatanker". On the right side of the search results, there is a section for "Sponsored Links" with three advertisements: "Prostaatanker" from Steun Onderzoek, "Prostaatanker" from Word Donateur, and "Prostaatanker?" from De nieuwste daVinci behandeling.

Figure 13: A Google search with the key word *Prostaatanker* [prostate cancer] and sponsored information about the da Vinci operation on the right-hand side.

Redirecting the patient's reasoning

Following the diagnosis, the patient probably becomes more sensitive and receptive to seeking information about treatment. Studying patients' forums reveals that the negotiated advantages of RARP in the public domain are to a large extent similar to those discussed in the professional arena, i.e., the RARP's technical superiority and its minimal-invasiveness. These two main characteristics are subjected to considerable promotion by both the manufacturer and urologists. Together they are able to override any doubts the patient may have about the superiority of RARP in eradicating cancer. In other words, the discourse on whether the cancer would be cured with the da Vinci system is replaced with the more pervasive arguments such as the reduced invasiveness of RARP and its technological accuracy. Therefore, the patient is consciously or unconsciously moved to give a priority to these aspects in making the final decision. The following quotes from a patient clarify this process (P3 in annex c.):

Making a choice is difficult. There are two different things we have to bear in mind: (A) the cancer has to go away, and (B) how comfortable are you once it has been done. Well, there is the risk that the treatment will go wrong, but you will always have that with any treatment. You only know *after* the operation whether you're cancer-free or not. . You don't know if or when it will come back. So you choose a method that gives you a chance of a better [quality of] life after surgery. It also depends on you as a person and how you look at the world and at life. ... I said to myself: "Harry, what do you want from life?" And in the case of prostate cancer, I come down to sexuality. I don't know whether I would have made the same decision if

I were ten years older. ... I wouldn't want to blame myself retrospectively for the fact that I had acted neglectfully towards this situation.

...

And I believe that the machine can work accurately; it can do that simply because of the new technology. ... It is a matter of luck and everybody has to be lucky [for a good cancer treatment result], but the luck factor is reduced when a machine is used rather than the human hand.

Interestingly, developing expectations with respect to da Vinci surgery applies not only to the choices of prospective candidates. It may also bring about a sense of 'regret' to patients undergoing operations via other methods.

I truly feel it is a real shame that any patient who has undergone what I refer to as 'conventional surgery' did not have the opportunity that I have had [with RARP] (Intuitive Surgical website, quoting a patient).

The patient's quote in the Intuitive Surgical website seems to go beyond mere promotion, as it is addressed by the board-member of the prostate cancer patients' organisation as well.

A lot of people call the Assistance Telephone Line of our association and say: "I have had bad luck because I was operated on three years ago with open surgery, when there was no robot". There is no such thing as 2nd rank treatment or 1st rank treatment, but people still think: "I wish I'd done it with the robot".

The urologists' recommendation to MIS

Sooner or later the patient comes to the urologist to seek his/her advice. With the current movement toward MIS in urology, which is described in a medical journal as an "unprecedented, undeniable trend" (Ghavamian 2009: 863), one can imagine that an increasing number of urologists will advise positively about MIS and recommend the da Vinci surgery (as the latest MIS method) accordingly. Notice what one patient (P1 in annex c.) says in this respect:

I'm from the military world [retired military officer]. From 1997 until 2006 I was monitored by urologists, and the disadvantage – or possible advantage – of being a military officer is that you have doctors who are fulfilling their military service, so that means that you [as a patient] have a new urologist every other month. So I had 11 urologists in six years! [In order to make a treatment choice,] I called all of them, because I had all biopsy reports and PSA measurements documented...all 11 of them said: "You should do laparoscopic surgery [and not open surgery]".

The ‘chicken and egg’ of surgeons’ recommendations and patients’ requests

Urologists in this study generally believe that, by the time patients come to them, many of them have already sought information and heard about the da Vinci robot from a vast variety of sources.⁶ The patient has therefore already developed a certain perspective about the relative advantages of RARP. It turns out from the interviews that this perspective is directed toward demanding da Vinci surgery more than conventional surgery. “Patients are ‘manipulated’. They are intrigued by the robot and all the publicity surrounding it. They think that it is the best therapy”, says a robotic urologist.

For this group of well-informed patients, the urologist’s positive recommendation to do MIS directs them to make their final decision in the direction of RARP. If the same recommendation is given to patients with no prior idea about robot surgery or those who don’t know which way to turn, then the doctor’s recommendation is what would shape the patient’s choice. Therefore, in any of these situations, the urologist’s advice plays a central role in shaping the ‘ultimate’ decision made by patient. As one patient (P4 in annex c.) puts it:

I had a couple of choices: (1) do nothing, (2) radiotherapy, (3) an operation. So I asked what radiotherapy is, and they told me it is six weeks of beaming, five times a week. And after a week you may think: “Is that all? It’s not that bad”, but then the complications start. ...[the patient’s wife continues:] We asked his doctor: “What would **you** do?”, and he answered: “I would have an operation; but go home and think about it for a week and come back next week and tell me what you want”. But my husband said: “Write it down. I already know what I want.”

...

[The patient:] You are sitting in front of a person with experience. When he says, “Operation!”, then you just do it, because I cannot say ‘no’. Then my doctor said: “You’ll be operated on by a robot” and that was the first time I had heard of it. Then I thought: “Perfect (*prima*)! That will be more accurate.” A human hand might shake. Five weeks later I was under the knife.

Urologists’ direction of information-giving

An in-depth discussion with patients also shows that when giving information to patients, urologists are sometimes selective in trying to convince patients that what ‘they’ do is probably the best. “Doctors make perfect sense when explaining why they believe that the method they use is the best one” (the Prostate Cancer Infolink weblog). As described

⁶ Depending on the patient’s age, education, and cognitive state, he may actively seek information from a variety of sources in addition to his doctors (family doctor, urologist, and oncologist). These include the Internet, the media, patients’ organisations, patients’ forums, former patients with (prostate) cancer, medical information agencies, (intimate) family members, friends, neighbors, colleagues, etc.

by one patient (P1 in annex c.) in this study:

Some weeks ago, I was at a meeting in a hospital. The urologist there gave a Powerpoint presentation demonstrating how great the robot is. I spoke to him during the break. I asked him: "You created a very nice image of that thing." "Yes", he said, "and so we should, because we are going to get one here." It's made more beautiful than it actually is. I mean all those stories about how the nerves are better, and the continence can be better... (board-member of the prostate cancer patients' organisation).

...

The stories are not wrong. They [just] don't tell you everything. And that counts for all new treatments. If you look at HIFU or Brachytherapy, you'll get positive stories. Unless you go right to the end of the list and hear about the side effects, you think that there is nothing better than that. ... It always starts like this: someone who adopts the new therapy wants to advertise it, otherwise they wouldn't have begun with it in the first place. So it's always coloured. I'd expect organisations like the *KWF Kankerbestrijding* [Dutch Cancer Society; organisation for cancer funding, research, and education] to come up with some comparative stories with all the pros and cons. ... My experience is that doctors don't tell you about all the different methods and the pros and cons of each of them. ... (P2 in annex c., also restated by P3.)

...

But theoretically, and according to their professional code, I expect them to explain the advantages and disadvantages for any treatment option, but there is always the question: "What would *you* do doctor?" And then there is a certain direction that they clearly go. ... If they were to tell you, well, there are some methods in their hospitals and some other methods in other ones, and these are the pros and cons of each method, then you would actually be able to make a decision (P1 in annex c.).

Solution for further problems

The availability of treatment for possible complications after robotic surgery can also be part of negotiations towards RARP. A patient argues how his urologist reacted to his concern about his sexuality by offering another treatment option for possible sexual complications following RARP.

... when I asked the robotic surgeon: "Well, what about sexuality?" he replied: "Don't worry about that anymore; there are so many methods available for that. If it doesn't work out, I'll inject you [direct penile injection for an erection] so you can F*[...] the whole street." Thank you doctor, but that is not what I call 'information'! [Rather irritated] (P3 in annex c.).

Articulating the surgical experience

All patients in this study strongly believe that, for them, a surgeon's experience is the most important factor in determining the choice of surgeon. "If you ask me why I chose for laparoscopy, I didn't choose for laparoscopy, I chose for my urologist's experience" is a typical quote. In fact, patients do not always demand merely the latest technology, but also the surgeons' experience and skills. Doctors and medical professionals themselves also emphasize the experience factor when referring patients to other surgeons or colleagues.

Consider this conversation with a robot surgeon's assistant:

[Interviewer:] which surgeon would you choose for your father if he got prostate cancer: a young robotic surgeon or an experienced laparoscopic ones?
[da Vinci theatre nurse:] I know that I'm a reasonably intelligent person and I wouldn't be fooled by the commercial presentations and I would go for the most experienced one who has done with the learning curve. ... And I hope that ordinary patients would also go for the usual laparoscopy in this case. But as you can see, things are changing and everybody wants the latest thing.

And this is the perspective of another patient (P2 in annex c.):

I agree that experience is by far the most important factor. ... But if everybody were to choose experience, there would be no new technologies and in the long run we would be faced with a problem. I also agree that doctors have to do a lot of operations just to get experienced, but preferably on other people [and not on me].

In such a situation, evidence of an acceptable level of experience with the new therapy becomes a remarkably important argument for convincing patients to undergo RARP. But how do robotic surgeons articulate their experience given the recent emergence of this procedure? Urologists who have completed the learning curve of the da Vinci surgery advertise the fact that they have passed it. Those who have not yet completed it explain the sufficiency of their prior experience and competence, using such arguments as the following. A patient explains (P3 in annex c.):

I was operated on by Dr. X. I did research on the experience of doctors with robot surgery. ... You know, it is new.... And he told me: "Well, I haven't done that many operations with the robot, maybe just a hundred, but I did assist during four hundred robotic operations in America". Should I also put that down in an account of his experience?

Interestingly, urologists who have switched from LRP to RARP argue on the basis of the prior experience they gained with usual laparoscopy. A board-member of the prostate cancer

patients' organisation adds:

I was there when they introduced the robot in hospital X. Dr. Y said: "I don't have a lot of experience with the robot, but because I have worked for a long time and done a lot of operations with the normal laparoscopy, I know how the prostate looks from the inside, I have it all at my fingertips, so it will be easier for me to become experienced with the robot quickly. I haven't come across something that I couldn't get to know". So he only had to practice cutting and sewing with the robot.⁷

The dependency of the patient's choice of therapy on his urologist's advice is predictable within the context of doctor-patient relationship. What is noteworthy with regard to the construction of demand is that although urologists consciously or unconsciously influence a patient's decision for RARP, almost all of them believe that it is the patient who initially demands RARP. The demand (the patient's final choice) for RARP thus reflects a combination of a patient's personal interest (built upon the information he gets through communications in his life) and the urologist's personal interest expressed through his/her professional authority.

I have realised that a patient's choice is also determined by commercial dependency. I mean if a hospital purchases a robot, they [the doctors there] then advise you, [albeit] with extreme discretion, that you should choose the robot, whilst telling you a nice story about it (board-member of the prostate cancer patients' organisation).

This co-construction of demand in the urologist-patient relationship is also expressed by insurers. Advisors of two insurance companies describe it as follows:

Patients come to us to ask if we will pay for a new therapy, but it is the doctors who tell them to ask us. They are induced by their physicians. Of course, nowadays patients are looking for the best therapy, no matter where they can find it, in Den Bosch, Amsterdam or Belgium. ... We do not know what makes the best treatment of prostate cancer (insurance company advisor).

...

I think it is the medical specialists who want the robot. They go abroad and see the technique at congresses or they are informed by their colleagues. Then they want to have it themselves (advisor insurance company).

⁷ The direction of surgeon's hands movements to move devices in robotic method is opposite to that of LRP.

The processes examined in this section are able to ‘sharpen’ the choice of both well-informed and less-informed patients to undergo RARP. The perception of the risk of prostate cancer and the urologist-patient interaction (advice for MIS method, the astute articulation of experience, and the projection of urologists’ interest through their professional authority) may, in combination, rule out other treatment options and make up patients’ minds in favour of RARP, hence, contributing to the construction of demand for it.

2.f. Shaping the public’s expectations

The mass media

Health care is a public concern and the mass media (visual media and the press) host much information about different aspects of health care including new forms of care. It is almost self-evident that the mass media influences the public’s perception. In the public sphere, it is the mass media that provide a ‘master forum’—a forum that can overshadow many others in shaping public discourse on certain issues (Ferree et al. 2002). This section describes how the image of new forms of care, including the da Vinci robot, in the mass media influences the public’s expectations and can enhance demand for them.

The following quotes and reports provide an insight into how the da Vinci system has come into the public sphere. From among the many examples, some have been taken from interviews, TV programs, news reports and Dutch newspapers. These examples are cited here in order to pose a critical question later on.

When a well-known Dutch astronomer comes to the night-talk show ‘Pauw & Witteman’ on TV, talking about how he underwent prostatectomy with the robot in Belgium, you expect this to influence patients. ... A popular singer also underwent robot surgery (interview with a robotic urologist).

...

The media were invited to an opening ceremony during which the da Vinci system was introduced into hospital X, as well as the governor of the province who cut the blue ribbon. ... They made a real show of it, with a lot of hustle and bustle. This was a way of drawing the attention of people and giving information to them (board-member of the prostate cancer patients’ organisation).

In an American TV program called “The Doctor “, a gynaecologist surgeon is talking about the da Vinci robot.

[The presenter asks:] I have heard that you are not just excited with the technology, you are **in love** with it?

[The surgeon, pointing to a picture of the robot:] This tool is just amazing. You still need everything in your brain but it just makes more difficult surgeries so much easier. You [the surgeon] feel totally in touch with the robot and you feel that these [robotic arms] are your hands. ... I believe in future every OR in the country and every gynaecologist [would have that]. ... this is the way we should be doing hysterectomy. ...

...
 'Doctors save lives by Remote'. ... It's called robotic surgery. Over the last several years it is become very popular. Patients often travel hundreds of miles to have this type of operation performed. ... Only weeks after [his] operation Tommy [the patient] is back to his lifestyle. And best of all, he is cancer-free.' (CNN News report, brought by Intuitive Surgical.)

...
 '...a month after [the operation], Garry is enjoying a cancer-free life. ...' (NBC5 report on a patient who underwent da Vinci surgery, brought by Intuitive Surgical.)

Slimme robot ingezet

♦ Hulp bij operaties prostaat­kanker • Kortere wachttijden

Op een scherm zijn alle handelingen nauwgezet te volgen. Voorzichtig wordt bij de patiënt op de operatietafel een stukje tumor op de nier verwijderd.

Uroloog Sjoerd Klaver zit twee meter bij de operatietafel vandaan en bedient met een soort joystick de robot die met z'n 'tentakels' de operatie uitvoert. Het Maasstad Ziekenhuis gebruikt als eerste ziekenhuis in de regio de Da Vinci robot voor operaties bij prostaat­kanker en nieraandoeningen.

De inzet van de Da Vinci robot lijkt op een kijkoperatie, maar biedt volgens het ziekenhuis meer voordelen. "De instrumenten kunnen meer bewegingen uitvoeren. We kunnen op de millimeter nauwkeurig werken", legt Klaver uit. Hij heeft in een Leuven ziekenhuis twee jaar ervaring opgedaan met de robot. Tijdens het opereren kijkt hij in een soort machine die een heel nauwkeurig 3D-zicht geeft van de buik. Met de Da Vinci-robot wordt de wachttijd voor een operatie voor prostaat­kanker bovendien flink verkort. Zo kun je binnen een week op de poli terecht en binnen vier weken door de robot geopereerd worden. De hersteltijd is een stuk korter en het is minder



"We kunnen met de Da Vinci robot op de millimeter nauwkeurig werken." Uroloog Sjoerd Klaver.

Een op de zeven

Van alle mannen die kanker krijgen, krijgt een op de zeven prostaat­kanker. Jaarlijks sterven hier zo'n drieduizend mannen aan. Het komt vaker voor bij mannen in West-Europa en de Verenigde Staten. De oorzaken van de ziekte zijn vooralsnog onbekend.

pijnlijk dan bij traditionele operaties. Volgens OK-teamleider Cees Merks worden in de toekomst

meer robotten ingezet bij operaties. "De beelden kunnen ook naar andere ziekenhuizen

gestuurd worden, bijvoorbeeld voor een second opinion of overleg. Dat gaat in de toekomst veel vaker gebeuren."

Kijk voor meer informatie op www.maasstadziekenhuis.nl/prostaat­kanker.

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Figure 14: Metro, the Netherlands 13-03-2009 [The title: The Intelligent Robot Is Put into Use]

Dokter wordt hightech

Snijden in patiënten is steeds vaker overbodig. Met millimeterprecisie gaan operatierobots via natuurlijke holtes bij de patiënt naar binnen. De chirurg van de toekomst is evenveel dokter als ingenieur
DOOR SVEN DE JONG

Op de operatietafel ligt een patiënt onder narcose. Boven de tafel hangt een gevaarte met tien robotarmen, allemaal voorzien van een ander instrumentje. De mannen en vrouwen in groene jassen



nieuwe technieken en op afstand bestuurbare instrumenten kunnen bestaande operaties een stuk prettiger maken voor de patiënt. Vooral de mini-



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den te leren die chirurgen nodig hebben. En de voordelen van VR-trainingen boven trainingen op simulatoren en patiënten creëren

Figure 15: *The Spits*, the Netherlands, 12-06-2009 [The title: The Doctor Goes High-tech]

Zelf opereren met twee joysticks van de Da Vinci Robot

► Onlangs honderdste prostaatoperatie uitgevoerd door 'superrobot' ► Sneller herstel voor patiënten

De armen van de Da Vinci robot bewegen over de operatietafel. Met een soort joysticks waarin je duim en wijsvinger steken, worden vier robotarmen op afstand bediend.

Er worden tot op heden vooral prostaat- en nieroperaties mee uitgevoerd. Maar voor een keer mogen niet-chirurgen het apparaat van anderhalf miljoen euro bedienen. Op de operatietafel geen patiënt maar elastiekjes, paperclips en wattenstaven.

Het gaat eigenlijk best gemakkelijk. Door het bewegen van de joysticks, gaan de robotarmen alle kanten op. Na een beetje oefening en concentratie kun je, door in duim en wijsvinger te knijpen, al iets beetpakken of doorknippen.

"Dit is het mooiste speelgoed dat er is", zegt uroloog Diederik de Lange van het Rotterdamse Maasstad Ziekenhuis. Via een speciaal beeldscherm zie je alles in 3D en dat biedt perfect zicht op wat je doet.

De toepassing van de Da Vinci-robot lijkt op die bij een kijkoperatie, maar biedt meer voordelen. Zo kunnen de instrumenten meer bewegingen uitvoeren en wordt op de millimeter nauwkeurig en zonder trillen gewerkt. Maar je behoudt alle voordelen van een kijkoperatie.



Een operatie duurt gemiddeld drie uur. Volgens uroloog Sjoerd Klaver herstellen patiënten ook een stuk sneller.

 **BARBARA DE JONG**
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prostaatoperaties zijn tot nu toe uitgevoerd met de Da Vinci Robot. Gynaecologen opereren er sinds kort baarmoederverzakkingen mee.

Figure 16: Metro, the Netherlands 06-10-2009 [the title: Self Operating with Two Joysticks of the da Vinci Robot]

Common characteristics of health care reports in the mass media

What do the above reports have in common? This is the question discussed with a number of Dutch health care journalists to see how published media reports about new forms of care such as da Vinci surgery can influence the public's expectations. The journalists interviewed in this study point to some common features of health care reports and refer to them as 'mainstream journalism'. They are described below.

Seduction

Perhaps, the most distinctive feature of many health care reports is its seductive content and/or appearance. Seduction is believed to be a pre-requirement in many journalistic writings about health care.

When the audience of a report is the general public, the report should contain 'fascinating' components that catch the public's eye immediately. Enormous efforts are undertaken to make a text fascinating and to make the readers impressed by it. ... You have to penetrate the bombardment of data in order to get your report noticed (interview with a health care journalist).

The journalists all agree that much of this seduction is achieved through the choice of the image and the headline of a report because they catch the attention immediately. The image subtracts the 'essence' of the text and 'manipulates' the audience to go through the report. After all, "if you are a freelance journalist, you have to 'sell' your reports and the editors [only] want spectacular stories" says a freelance medical journalist.

Exaggeration

Catching the public's attention in itself sometimes requires strengthening the story.

Seducing the reader is only possible by writing attractive stuff about the topic particularly in the beginning of the text. ... That is why vague arguments about new treatments are sometimes presented in the media as if they were 'facts'. ... Sometimes I interview scientists and let them read what I have written. They are enthusiastic about it but sometimes they try to soften the findings ... I feel disappointed when they 'kill' the story. ... Once I wanted to write about a new lens. How could I make it fascinating? I had to get the attention of the public by arguing, for instance, that in future you would no longer need glasses. But when I talked to ophthalmologists, they told me that making a [new] lens is one thing, putting the lens in the place and enhancing a patient's vision is another. ... (interview with a health care journalist.)

Optimism

According to journalists, a health care report about a new innovation usually begins with optimism. "You cannot start with cons. You have to start with optimism, not with uncertainties. ... Otherwise, there is no reason to write" said one of them, and he continues "...and if you don't take this into account, the editor will change it". The argument goes further:

The 'mainstream' always starts with optimism ... and it only needs some disasters [e.g., the emergence of serious complications] to stop writing in the mainstream.

...

If you write about uncertainties or stories about older therapies, it would be boring and wouldn't attract as many readers because people often read [i.e., understand] what they want to read. If you have got cancer, you just want to get rid of it as fast as possible [and you would like to read a report that confirms that this is possible].

...

I often find writing about health care much more frustrating than other issues because there are too many things you are supposed to take into consideration; how much do we know at the moment about a new intervention? How uncertain is its effect and safety? What does it mean to different people? What does it replace? How much does it cost? ... But so often there is simply no room to be that critical.

Responsiveness to the public's taste

A good health care reporter probably takes an interactive approach 'from the public to the public'. In this study journalists believe that for emerging health care innovations, much of the public's interest and curiosity is oriented towards a technical mechanism of action — or how the new thing works — rather than how well it works. Accordingly, when writing a report on emerging interventions, a journalist will probably follow the same direction.

You can seldom think of writing about non-technological aspects of health care innovations. It is a difficult and somehow boring subject. No one would read it. For example, writing about the DBC system [financing innovations] is very important but it is a very broad, complex and boring subject. Even an economic editor would not be interested in it. It is difficult to conceptualize and write about it. It is not sexy. Moreover, you would also have to give too much basic information to make it understandable.

Early announcement

A decision to write about a certain topic, such as da Vinci surgery, is made based on discussions in medical journals, press releases and information journalists occasionally receive from medical professionals. The early recurrence of signals about the da Vinci robot from all three of these domains can push a journalist to address this 'Topic of the Day'. Quotes are clear enough:

I agree that sometimes health care journalists write about new technologies too early. ... There are a lot of questions about the use and effectiveness of these technologies. ... But you know that the subject is very sexy: the robot, the laser, the genes. ... On the other hand, you get too many press releases about all sort of new treatments and how promising they are. Some hospitals are very active in doing that and they often

start by making a lot of fuss about new therapies. With the present market-like system, they have to sell themselves. ... You eventually see that, at a certain point of time, when the topic keeps return again and again; then you feel that it's the time you should dig it.

...

Sometimes I tell myself, O.K., so this intervention has emerged but let's not announce it now but after a year and see where they have been going with this new intervention. As a journalist you have to be even more aware than in the past. But there is also the 'pressure' to write early from journalists themselves, because if I don't write about it, another journalist will.

The innovation to mention; the 'news value' of the da Vinci robot

Robot surgery may be a desired topic to be covered by journalists because it presents a high news value. First because it is a state-of-the-art (*actueel*) high-tech innovation; it is the future. "I remember, I wrote about usual laparoscopic surgery about ten years ago when it was really new", says a journalist. Second, it is related to health care and health care is a special issue to write about because it is regarded as a concern of all and at the same time it is a science-based issue. Third, surgery/operation may be in itself an attractive issue to address. Last but not least, it is all about cancer, the treatment for a cancer and the treatment of a common cancer. By bringing together all these elements 'state-of-the-art', 'high-tech', 'medical', 'innovation', 'surgery' and 'cancer', journalist are able to create quite sexy and beautiful stories about da Vinci surgery.

In sum, 'great expectations'

When a health care reporter decides to announce the da Vinci robot, he/she is at the same time a player; a stakeholder in the field because she *chooses* at this point in time to raise awareness about the existence and benefits of da Vinci surgery, *among other* therapies, and to highlight certain aspects of this treatment *among other* aspects. This is probably not the case with conventional therapies as they lack news value and do not often conform with mainstream journalism. Discussions about established therapies (and existing evidence of their implementation) make less of an 'appearance' in public spheres such as mass media (unless when they are to be positioned against new therapies). Such discussions very often remain limited to certain scientific journals.

This indicates a certain direction of the publicly-available information about da Vinci surgery in influencing the public. In as far as the topic of da Vinci surgery fits in with the mainstream journalism as described, the very availability of information will cause da Vinci to be heard more, searched more, and demanded more accordingly. Equally important, the

content of the information provided through mainstream journalism will be directed toward shaping great expectations!

2.g. Da Vinci surgery as 'the way to go'

Within the context of care delivery, the sense of need for RARP reflects the perceived advantages of this method. The advantages imply a variety of concepts such as the desire for progress and innovation, technological advancement, state-of-the-art care, clinical excellence, minimal-invasiveness, reputation and prestige, competition and differentiation, profit, production of science, professional career opportunities, fascination and precision, and comfort and ease. These characteristics satisfy the interest of many stakeholders and leave little room for any further hesitation by potential adopters. The sense of need is thus created, and more noticeably, disseminated in the interrelation of stakeholders.

A striking feature of the construction of demand within this context is this: while stakeholders apparently have the 'choice' to adopt RARP rationally, their enthusiasm brings about a sense of 'inevitability' in demanding RARP, because it is seen as 'the way to go'. Intuitive Surgical's website quotes a da Vinci surgeon, who was also a da Vinci prostatectomy patient. He expresses this inevitability.

The decision was open surgery versus da Vinci prostatectomy. And when I looked at what I had been doing and [saw] the outcome of my patients, it was a **no-brainer** (Intuitive Surgical website quoting a urologist).

The word no brainer, chosen for the title of this report, represents metaphorically the conceptualisation of da Vinci surgery as the way to go. This seems central to the sense of the need for it. In the next chapter we shall examine what may happen in this 'way to go' and see how the perception of an inevitable need may influence the implementation of RARP.

3. THE AFTERMATH OF PURCHASE

In the previous part, the construction of the sense of need to implement the da Vinci system was described in detail. This part traces demand further. The first two sections explain a transition in the perception of need after purchasing the da Vinci system. The last section describes a different conceptualisation of the benefit of RARP after purchase.

3.a. Planning for implementation

'Planning' to meet preconditions afterwards

Successful implementation of the da Vinci surgical program is a complex task and requires taking into account many considerations such as financing arrangements (for both the purchase and the costs per operation), capacity (building), surgical and/or technical personnel training, hiring/training a robotic surgeon, facilities (building and accessories), and perhaps publicity. A number of respondents, namely a hospital manager, an insurer and two urologists, believe that planning for an effective implementation of robotic surgery often only comes to mind after rather than before having purchased the device. The perception of an inevitable need to purchase RARP may avert meeting all the basic preconditions for implementation. As one hospital manager describes it:

What happened in this hospital is that they first bought the robot because they really wanted to have it in-house and then thought about what to do with it. ... They did not meet the basic preconditions such as safety issues, technical facilities in the OR, personnel training, maintenance, etc. They did not have a good plan beforehand about how they were going to implement the robot and how and for which subgroup of patients the robot was going to be used. ... They did not have sufficient personnel resources and facilities, and this is the case in many hospitals in the Netherlands. These issues should be also part of the implementation plan [taken into account before purchase].

Over-estimation of the overall capacity

For many Dutch hospitals, the prospective plan to implement the da Vinci system will mean an increase in the number of operations up to about 250 RARP procedures per year. Achieving this target can be seen as an assurance of acquiring sufficient surgical experience in the short term but more importantly of attaining the break-even point for costs in the longer term. A case in point is a business case, drawn up by the urology department (*vakgroep*) of a hospital, to negotiate the purchase of robot with an insurance company. The current rate of prostate operations (LRP) in this hospital is around

hundred per year. In this business case, the hospital expects an increase in patient input from the current amount of around hundred cases to some 250 cases after the introduction of the da Vinci robot. A more frequent use of the device is financially desirable for the hospital not only for returns on the investment but also to reduce the total costs per procedure and thereby increase profit.

A crucial question here is whether this financial justification is aligned with the epidemiological pattern of prostate cancer. Literature suggests the appropriate candidate for RARP to be a patient younger than seventy years, with a truly localised prostate cancer (in T1 or T2 pathological stage), and without co-morbidities such as inguinal hernia or severe overweight. It is clear that if all ten current da Vinci centres in the Netherlands want to reach the break-even point for costs, there should be around 2500 cases for robotic prostatectomy per year to meet this point for all centres. However, between 2003 and 2007 the average annual number of total and radical prostatectomy operations in the Netherlands amounted to 1438 cases for all methods of operation (hospital statistics Prismant website). Moreover, the incidence of prostate cancer seems to have remained steady, as evident between 1996 and 2003 (RIVM website), or increasing very slightly later on (KWF report 2004).

Now let us make a simple calculation based on the current national rate of radical prostatectomy operations (the above figure; see also annex e.). If no any other hospital plans to purchase the da Vinci system; and if no patient whatsoever undergoes ORP or LRP in the whole country; and if no Dutch patient whatsoever undergoes RARP outside the Netherlands; and if patients are distributed evenly among all ten hospitals, then there would be, on average, less than 150 cases suited to RARP per hospital, per year. This is clearly less than the expected 250. Even more importantly, it is obvious that the above assumptions are not all realistic. A board-member of the prostate cancer patient's organisation explains capacity from the opposite perspective:

In Holland, we have about 1200 prostate cancer patients who need to undergo an operation, two hundred of whom have to undergo open surgery [thus one thousand candidates for MIS; the statistics come from the prostate cancer patients' organisation]. If you take a working week of five days and fifty working weeks a year, you have 250 working days. How many robots do you need then? If you do, on average, one operation a day [to reach 250 cases per year], four robots are more than enough, at least in the short term.

In in-depth discussions about their estimated capacity, not a

single urologist, hospital manager, or insurer points out the relevance of the epidemiological pattern of the disease in their arguments. Nor was there any reference to this point in the above-mentioned business case.

Unsuccessful centralisation

One possible strategy to meet the capacity target could be to consider the centralisation of RARP to a limited number of hospitals across the country. A centralised provision of RARP is recommended by the literature as well (Camberlin et al. 2009). However, respondents believe that the centralisation of RARP have been unsuccessful in the Netherlands because an increasing number of hospitals may consider moving towards a centre of excellence due to the capabilities that the da Vinci robot offers, i.e., being a favourite platform for competition, status, and techno-scientific progress in addition to patient treatment. By virtue of its having the da Vinci system, one non-academic hospital has sought being entitled as a teaching hospital (*Samenwerkende Topklinische opleidingsZiekenhuisen, STZ centrum*). The centralisation of RARP seems structurally inconsistent with the current market-oriented health care system, in which providers and insurers have freedom to decide whether to provide (B-segment) care. According to an advisor of a health insurance company:

We thought about making contracts with a limited number of hospitals. But we saw that more hospitals wanted to have robot surgery. You cannot stop this process because they want it and CVZ has also issued positive statement about it. ... When we contracted hospital X, we asked (required) them to arrange a referral system so that patients who need robot surgery would be referred to them from neighbouring clinics and hospitals (which do not have robot). We thought that if there is one centre in any region, patients will be referred to that centre. But this system did not work. Doctors themselves send patients to any hospital they want and we cannot send them to a certain hospital. In the first eight months of the contract, we expected some 70-75 cases in that hospital, but there were no more than thirty patients who underwent [RARP] surgery.

Supply-induced demand

Since it appears that the centralisation of RARP is not feasible and many others may be planning to 'join the club', a more fragmented provision of RARP is anticipated. This, in turn, may lead to a supply-induced demand. Similarly to the classic example of road transport: the presence of new roads may result in some additional traffic. This makes meeting the break-even target for costs even more difficult.

The quest for experience and evidence

It turns out from the interviews that seeking assurance of returns on investment is not the only incentive for expanding the capacity of care delivery. Gaining a scientific reputation

with the da Vinci platform may also lead hospitals — particularly, but not exclusively, academic centres — to perform more operations. Firstly, they need to gain more experience in the shortest possible time in order to improve surgical outcome (better oncological result and fewer complications), and complete the learning curve. Secondly, there is a great global and local need to produce more evidence of effectiveness of the robot for scientific purposes such as publication, conducting research, teaching, expanding scientific collaborations, and attracting research funds. The more patients undergoing surgery, the more (powerful) evidence of effectiveness can be produced.

The technological imperative

A technological imperative involves the conceptualisation of a technological capability as an operational ‘requirement’.⁸ In other words, it refers to a tendency or an imperative to utilize technology because it is available and technically possible, rather than because it is necessary. With regard to da Vinci surgery, it involves this idea: ‘now that we have the robot and *can* operate with it, we *should* do so’.

Facing a new pressure

Returns on investment, over-estimation of the capacity for RARP, and the infeasibility of its centralised provision may pose a challenge in implementing the da Vinci system. Together with the technological imperative, they may lead to a strong tendency to do more operations with the robot, i.e., an imperative to attract more patients. In fact, before purchasing the da Vinci robot, stakeholders are faced with the pressure (remarkable sense of need) to purchase this device. When the device makes its appearance, they continue to face a pressure, though now it is a different one. This time, the ever-expanding use of the robot (doing more operations) comes into effect. The need to purchase is now replaced by the need to do more. How could care-providers position themselves in the face of this new pressure? It is described in more detail below.

3.b. During the course of implementation

In search of the patient

Whereas the financial justification for using RARP presupposes a certain number of procedures per year, to date, this target has not been achieved in many hospitals with the da Vinci robot. Head of department of medical technology of an academic hospital highlights a potential dilemma in the realisation of this target:

...for instance, you might calculate that you would need more than two hundred patients per year, but you have to get them. You could ‘create’ patients but

⁸ Technological imperative implies that because a particular technology means that we can do something (it is technically possible) then this action *ought to* (as a moral imperative), *must* (as an operational requirement), or inevitably *will* (in time) be taken (Chandler 1995).

that's not a good way. That is the problem with big investments like this. On the other hand, there is another limitation. You have to take care not to use it for everything. If you use it in this way, I think it would be no more than an expensive "toys for boys". ... Then, if they tell you that you have to have your prostate removed, you cannot be sure if it is the best necessary therapy for you or if they just want to have another patient.

Less stringent pre-operation evaluation

There is a potential for a less strict evaluation before operation by expanding the eligibility criteria and including more candidates for RARP. This includes particularly patients with borderline cancer profiles. When interpreting laboratory and pathological tests, the urologist may decide to kill three birds with one stone: to be on the safe-side with cancer treatment, to meet the pressure to do more, and probably to satisfy the patient by alleviating his anxiety of living with 'cancer' (see also section 6 of part 2). The surgeon may, therefore, feel less obligation to meticulously weigh up the indication for an operation for patients with a borderline profile. Here is the reaction of a board-member of the prostate cancer patients' organisation:

The problem with prostate cancer is often not the treatment but the diagnosis [pre-operative evaluation based on prognosis]. They [urologists] make a lot of mistakes at this point. If you don't have a clean operation area [cancer-free tissue margin after removing the prostate], meaning that the prostate is gone but the cancer is not, you've had a bad diagnosis before the operation and they haven't evaluated you well enough to see if you were a really good [candidate] for that operation. ... [Discussing this issue with urologists,] I sometimes heard their reaction [objection]: "Why are you meddling in my affairs? I'm the doctor and I'm supposed to know what I'm doing." But we are not meddling in medical affairs. We are only meddling in the process. The process by which a patient who gets diagnosed with a high PSA goes through treatment and becomes an ex-patient. ...

Over-treatment

Some respondents point out the potential 'danger' of over-treatment as a result of the pressure to do more operations. Two panellists of the 2009 EAU conference expert panel, including a Dutch urologist, clarify this issue:

[This] is a problem. With the emergence of so many laparoscopic centres — for instance two centres in my city with 150,000 people — there is a huge risk of over-treatment because they need to use the robot once they have it. This is a very big danger because young urologists are becoming less critical with respect to the indication, because they face the

pressure of the financial investments for the equipment. I can give you examples of patients I saw for a second opinion as a senior urologist. Patients with just a single biopsy with less than five per cent cancer cells, with a Gleason score of 6. ... This is a big danger and I am warning about it.

...

there is a huge problem [in the form of] over-treatment. Especially with new technologies, urologists will tend to be more 'aggressive' in treatment when there is no need to treat.

The tendency towards over-treatment also comes out in the discussion with the member of the board of the prostate cancer patients' organisation:

[Respondent:] What I see with the development of the robot is that the doctors and the urology department who were involved in purchasing and investing in the robot, they must have at least two hundred operations every year, so they will decide more quickly and easily to operate someone. That is the danger I see in technological developments like the robot. ...

[Interviewer:] ... If an increasing number of hospitals want to purchase the da Vinci system, there might not be enough [prostatectomy] patients for all of them. ...

[Respondent:] I think that with the amount of robots that we have — and the last one [the 11th] is coming, though there may be even more in near future — there will be no arrears, because everyone wants to use it. I'm more concerned about the situation that too many people will be operated on rather than too few.

Advocating mass screening for prostate cancer

Mass screening for prostate cancer involves measurement of the blood level of PSA at population level (usually all men between 50-70 years of age, Wymenga 2001). It is a controversial issue at the moment in both the Netherlands and abroad, and a matter for hot debate not only in the medical literature but also in the public sphere (Faulkner 2009; Boyle & Brawley 2009).

In the US, I have seen how some prominent senators, who had been diagnosed with prostate cancer, created a lot of media attention and the senate took a decision to initiate screening for prostate cancer without any scientific evidence whatsoever. I don't think this is going to happen in Europe because we have a totally different mentality ... (Expert panel, EAU conference 2009).

In the Netherlands, there is no mass screening program for prostate cancer running or planned in the near future (Dutch Ministry of Health). Dutch doctors can request screening tests for individual patients but they are not allowed to initiate mass

screening (expert panel, EAU conference 2009). The discussion as to whether to implement mass screening for prostate cancer is going on in the Netherlands among urologists and between the NvU and the Dutch Ministry of Health.

Mass screening for prostate cancer can be associated with an increased awareness of the potential risk of prostate cancer in middle-aged men (Faulkner 2009). Further propagation of this potential risk in society can lead to enhanced and often excessive public concern to demand a solution.⁹ RARP would be there to satisfy this enhanced concern. In particular, RARP would serve the fraction of population which will be labelled as suspect (borderline cancer profile) by a 'controversial detective technology' like PSA testing (ibid.).¹⁰

Since screening involves cancer detection at a younger age and in the earlier stages of cancer, it would secure enough patients with an ideal tumour profile for RARP, many of whom would turn out to be a candidate for RARP. On the other hand, operating on younger patients with smaller localised cancer promises a better outcome of surgery. This, in turn, can be readily translated into a witness for the superiority of the da Vinci prostatectomy.

It would, therefore, be reasonable to assume that robotic urologists will position themselves in favour of mass screening for prostate cancer and 'lobby' for it. Firstly, because they have an incentive to perform RARP and to do it more often and secondly, because the scientific controversy surrounding this program creates room for the lobbying of interest groups.¹¹ The interdependency of a successful da Vinci implementation and the prostate cancer screening program is explained by a da Vinci urologist and a da Vinci theatre nurse respectively:

Overall, fewer prostatectomies are performed in the Netherlands than in Belgium. The screening program in Belgium has had a significant impact in increasing the number of operation candidates per head of the population.

...

The belief of our surgeons is that when prostate cancer screening becomes routine in the near future, there will be more candidates for operation and the population of patients will be younger. For them, quicker recovery and sexual functioning are important. [Since they are in the earlier phase of cancer,] the surgeon will have more control over the tumour and thus their operation will be more precise. The robot helps them with little bleeding, a quicker recovery and

⁹ This phenomenon is referred to as 'schismogenesis' and described in the case of pharmaceuticals by Nichter & Vuckovic (1998).

¹⁰ PSA is basically a prostate tissue indicator and not a prostate cancer-specific indicator.

¹¹ Obviously, it can be only one incentive among others to argue in favour of mass screening.

saving nerves [to preserve sexual functioning]. ...

Counting on public resources

Implementation of the da Vinci robot involves a financial risk for both hospitals and/or insurers. This risk mainly applies to the costs of purchase and maintenance of the device. The burden of the financial risk, though borne by the hospital and/or the insurer, also rests partly on public resources. The fact that RARP is a collectively insured care (CVZ 2007a) means that an increase in the amount of use may partly reduce the financial risk of investment. In this situation, neither the hospital nor the insurer have a strong incentive to control (reduce) the amount of use. The hospital gets paid by the insurer for the costs per operation and the insurer is partly compensated via risk-adjusted contributions from the collective Health Insurance Fund. Similarly, possibilities for hospitals and insurers to reduce the existing financial risk are based on obtaining a greater share of the collective resources. For instance, the NvU is now considering a proposal to request a new declaration code for RARP, with a higher tariff, since the current tariff seems insufficient (interview with a board-member of the NvU). Another instance is the Intuitive Surgical's partnership program that supports hospitals in implementing the da Vinci system. This partnership program encourages hospitals to consider the impact of more provision of other services in a successful implementation of da Vinci system.¹² In the Netherlands, many of these additional services are also insured care.

The gain of a surgical patient provides more than just additional procedural revenue. It also drives ancillary service revenue. The patient touches several fixed-cost services within the hospital, generating revenue beyond just the surgery, through a rigorous work-up from biopsy [tissue pathology] to CT scan, or MRI. ... [Intuitive Surgical website].

After all, neither care-providers nor insurers have to exert effort to convince patients for any additional out-of-pocket payment for RARP.¹³

These processes point to a reduced financial risk of implementing RARP at the expense of collective resources. They suggest that the implementation of RARP is closely and largely associated with the intensity of its use; a tendency to perform a growing number of operations without there being a strong financial disincentive to counterbalance it. In the words of one insurance company advisor, "why not do more robot surgery, if the hospital, the surgeon and the patients are all happy with it, and the insurance pays for it?". It seems that

¹² This can also be an incentive to consider the purchase of da Vinci system.

¹³ The exception is if a Dutch patient wants to be operated outside the Netherlands. In this case, the health insurer may decide to cover only a part of the costs and require the patient to pay the rest.

after purchase, performing more operations with the da Vinci robot almost becomes a 'no-brainer'.

3.c. From optimism to realism

So far, this report has brought up a number of elaborated explanations regarding the drivers of the demand for RARP. This last section discusses a change in the perception of the need for RARP after the purchase. It reflects a somehow different conceptualisation of the benefits of this method during routine implementation.

Returning to a basic concern: the 'additional' benefits

An in-depth discussion with the chairman of the board and the urologist of a (usual) laparoscopic centre clarifies a critical distinction between 'the benefits' and 'the additional benefits' in justifying the need for the da Vinci system:

[Interviewer:] If there is the same incentive for too many hospitals, could you then expect the ever-increasing diffusion of the da Vinci device in the Netherlands, as in Belgium?¹⁴

[Hospital chairman:] Then the issue is the 'rat race'. If you know that the quality is far better, then you would go for it, but do you know for sure at the moment? Twenty years ago, we had the same discussion with the MRI. Now we say 'that's fine', but we have to have *another* [new] sort. Also with the CT and PET scan, it's the same discussion as for the robot, but we don't know at the moment. ...

[Urologist:] In this hospital, 'we have the handicap of a head start' ('*we hebben last van remmende voorsprong*'). We were ahead in laparoscopic surgery. We are one of the exceptional centres in the Netherlands that do more than one hundred radical prostatectomies per year. We have gained too much experience in that. The main question for us [and probably other laparoscopic centres] should be: "what would the robot add to that?" ...

The surgeon who is learning minimally invasive prostatectomy would get through his learning curve faster if he were to use the robot. That has been proven in the literature. But there is no proof that a patient who has been operated on using the robot will have a better outcome than a patient operated on by a skilled surgeon [with other two methods]. And we are skilled surgeons. We have passed a long learning curve. So there is only a little gain for us together with a lot of costs.

¹⁴ Camberlin et al. (2009) report that in Belgium, with a population of about ten million, the number of installed base da Vinci robots exceeds twenty sets in September 2008.

Yet, at the time of the field study, this hospital is negotiating the purchase of the da Vinci robot with an insurance company.

The comparative effectiveness

The author forwarded the question asked by the urologist (above) and put it to some urologists who have already implemented the da Vinci surgery. The idea was to determine whether surgeons who are experienced with RARP articulate its benefits in a similar way to those who wish to purchase it. It could also be a proxy in order to understand how far they come to a comparative approach in assessing the benefits of the da Vinci system. Respondents were asked, “what has the da Vinci system really added to the ‘whole’ package of care you have been delivering to patients with prostate cancer?”

The responses to this question reveal two tricky issues in perceiving the benefits of RARP. First, what the urologists stress in interviews, and particularly at the start of the interviews, is that many of the advantages of the da Vinci robot are not exclusive to the da Vinci system. It shares the advantages of the minimally-invasive method in general (and therefore cannot be a strong argument to switch from LRP to RARP). Second, during the course of implementation, there seems to be a shift in how they make sense of the advantages of the robot. Their answers reveal a discrepancy between conceptualising the benefits of RARP after use, and the mainstream discourse before the purchase (described in part two). The following issues are particularly suggestive of this discrepancy.

Uncertain long-term benefits

A da Vinci urologist, who has had prior experience with both ORP and LRP, pointed out the uncertainties inherent in the additional benefits of RARP in the long run:

The short-term effects of RARP, such as reduced bleeding, fewer hospital admissions, less pain, etc., have been mentioned in the literature, but the long-term outcomes, in particular, are more important:¹⁵ oncological cure [no tumour recurrence, i.e., the main aim of operation], incontinence and erectile dysfunction. The oncological cure rate is difficult to judge but it is about seventy per cent. Of course you have a second [additive] option, such as chemotherapy, as well. Incontinence is also difficult to judge because of the different subjective definition of incontinence per patient. For impotence, since the nerves are anatomically located very closely to the prostate capsule, in an attempt to do a margin-free excision, you may inevitably have to excise the nerves [resulting in erectile dysfunction]. Sometimes I say to the patient beforehand that “I might have to cut the

¹⁵ The cost of possible oncological complications in the long run might be times more than the gain in the short-term such as shorter hospital stay. From the perspective of collective financing, the former is obviously more important than the latter.

nerves and this will be 'my decision' during the operation". Looking at these long-term outcomes, open surgery is better than laparoscopic surgery [with or without a robot]. I always tell the patients that open surgery is still a very good choice.¹⁶

Concurrent improvement of the existing surgical techniques and methods

Whereas usual laparoscopy was a breakthrough innovation in comparison with open surgery, robot surgery is not. In fact, the move from open surgery to the laparoscopic method was a much greater change than that presented by robot surgery.

Further he continues: "On the other hand, open surgery has also benefited from usual laparoscopy in the sense that the techniques for open surgery have been improved from the lessons learned by usual laparoscopy. This is quite less evident in the case of RALP [experience with robot does not help improve the open surgery as much]".

Technical comfort

Another argument is that the use of da Vinci robot has just made the operation easier for 'the surgeon', technically and perhaps ergonomically.

[The technique of] open surgery is ascending. The prostate tissue is excised from the apex of the prostate to the bladder neck. Laparoscopic prostatectomy is by contrast descending and the surgeon starts from bladder neck then goes to the apex. With the descending technique, anastomosis and reconstructing the existing structures after removing the prostate is simply easier with a robot than during open surgery, ... especially if you feel tired at the end of an operation (interview with urologist).

Visual feedback in, tactile feedback out!

The three-dimensional visual image of the da Vinci system¹⁷ is a technical improvement over the conventional two-dimensional image. However, some respondents believe that, for the surgeon, it is just a 'replacement' of one sensory feedback with another. In fact, the robotic urologist who has gained an additional visual dimension has actually lost tactile feedback in the process.

They say that the robot has a 3-D image. Of course, it should have that, to compensate the lack of feeling [tactile feedback]. With usual laparoscopy, you know where you are inside the patient. A robot surgeon needs 3-D vision anyway (interview with an LRP urologist).

...

If you operate using the robot and a blood vessel is cut

¹⁶ However, later in the interview he tells that he does not perform open surgery for the prostate as well as adrenal and kidney any more. Nor does he teach residents the open method of prostate operation.

¹⁷ The third visual dimension adds the depth of field to the conventional two-dimensional images used in older generation of laparoscopy. The third visual dimension is, however, not exclusive to the da Vinci system. It can be compatible with the usual laparoscopic device as well.

and the blood is not promptly sucked away from the operative field, then the 3-dimensional and thirty times enlarged image of blood is still blood and you cannot use your hand [tactile feedback] to continue the operation (a board-member of the prostate cancer patients' organisation).

Inseparable dependency of the effects on a surgeon's experience

Intuitive Surgical profoundly promotes the technical accuracy of the da Vinci system:

The da Vinci system is designed to scale, filter and seamlessly translate the surgeon's hand movements into more precise movements of the instruments. [It] helps make da Vinci surgery look and feel like traditional "open" surgery. But this is where the similarities end (a transcribed multimedia in the Intuitive Surgical website).

Respondents agree that the net benefit of the da Vinci robot is closely intertwined with the surgeons' experience (knowledge and skills). This is also mentioned in the literature (Camberlin et al. 2009). Some da Vinci urologists in this study emphasise that the outcome of surgery is rather more surgeon-dependent than technology-dependent. In a robotic surgeon's words, 'it is really a "marriage" of the three fields of medical knowledge, skills and technology and the patient would like to have all three in one head'.¹⁸ This leaves no doubt that the net benefit of the device can always be attributed in part to the surgeon's experience; hence it cannot be evaluated in isolation (ibid.).

In a prostate cancer (virtual) social network, an MIS urologist and founder of that network advises patients who are baffled and torn between the da Vinci and other treatment methods. These quotes describe an opinion that is also shared by two respondents (urologists) in this study:

I am aware of no evidence that, in experienced hands, any of these devices is superior in terms of cancer control, blood loss, pain, hospital stay, erectile function, continence or anything else that would directly matter to you. If you are considering prostate cancer surgery, you should focus on who will do your surgery, not which gizmo [latest gadget] will do your surgery. If you are having minimally invasive prostate cancer surgery, find your "Tiger Woods" and don't micromanage the golf clubs.

...

Having done open [prostate surgery], laparoscopy and laparoscopy with da Vinci for 25 years, I can tell you this: from a technical point I have seen some magnificent results with all three techniques. If you come to me I will choose the tools that make *me*

¹⁸ A robotic surgeon during a multimedia presentation (Source: <http://www.orlive.com/davinci/channels/davinci-urology>)

satisfied. I will tell you that in *my* hands you will have a better result with minimally invasive surgery: much less pain and much less blood loss. I will tell you that you will have the same result whether or not I use the da Vinci in the minimally invasive surgery; and that the hospital will pay a lot more.” (Emphasis in original; Source: <http://prostatecancerinfo.ning.com/>)

Whereas before routine implementation the main argument revolves around the stereotypical benefits of RARP (described in part two), after using the da Vinci device, urologists may begin to turn their views to articulate what, if any, the additional benefits of RARP can be in their own specific situation (as opposed to a generic set of benefits of the device). This way of conceptualising the benefits of the da Vinci system indicates a turn towards a more ‘comparative’ and relative way of thinking when articulating the benefits. It renders a more realistic explanation in justification of the need of an expensive device such as the da Vinci system. From a financial point of view, for any given form of curative care, including prostate surgery, it is not a single element but the ‘whole’ package of the delivered care that is financed in the Netherlands (via the DBC system).

It does, therefore, make sense for *both* care-providers and care-financers to correlate the need for RARP to its additional gains (out of the body of demonstrated benefits). It is also a way of recognising a more real need, narrowed down by these crucial preoccupations. First, asking oneself: ‘aren’t our competitors doing what we are doing?’ Second, whether all less-expensive measures have been taken to optimise health gains for patients with a prostate operation before planning to purchase the da Vinci robot. In a more concrete sense: ‘When we go for da Vinci system, for instance, to reduce complications or the length of hospital stay for patients undergoing a prostate operation, have we already considered other, less expensive, improvements that could lead us to achieve the same goals?’

Strikingly, this critical approach is in clear contrast with the former discourse that represents the adoption of RARP as ‘the way to go’ or a ‘no-brainer’ (part two). As examined in this study, such comparative reasoning, if it plays any part at all, is usually evident *after* implementing the device, and not before its purchase. In fact, before implementation, the perception of the need to purchase the da Vinci system probably surpasses critical thinking of this sort. It does not receive due attention until after the purchase. Only when the sense of need has somehow ‘cooled down’, do the actual benefits of the da Vinci robot come to be realised in the form of its additional benefit (to the whole package of delivered care in a given hospital).

No [single] therapy [for prostate cancer] has been

shown superior to another,” an analysis by the RAND Corporation found.¹⁹ ... When I asked Dr. [X], who has studied the data, what she would recommend to a family member, she paused, then she said, “Watchful waiting”. ... But if the treatments have roughly similar benefits, they have very different prices. ... The country is paying several billion more dollars for prostate treatment than is medically justified — and the bill is rising rapidly. ... You may never see this bill, but you are paying it. It has raised your health insurance premiums (The New York Times 07.07.09).

It should be noted here that a comparative approach to evaluate the effectiveness of alternative surgical techniques, namely head-to-head comparison, is also not congruent with the mainstream epidemiological studies. A number of reasons are mentioned for the scarcity of this sort of epidemiological studies, for instance, the difficulty of randomisation, selection criteria, time and budgetary constraints for such trials, potential conflicting interests, and prioritising internal validity over external validity in many epidemiological studies (Camberlin et al. 2009; Elwood 1998; interview with a clinical epidemiologist). Conducting a head-to-head trial for surgical techniques would be considerably more difficult than for pharmaceuticals. Those involved in epidemiological research in academia as well as in the industry may not ‘choose’ to conduct a comparative study as such, since it would seem neither feasible nor in their interest. A urologist explains this further by stressing on the words ‘that little’:

When you want to achieve statistical significance to prove that one [surgical method] is better than the other, it would be easier to compare two techniques that result in a big difference. But there is only a small difference between [the overall effectiveness of] the laparoscopic and robotic methods. Such studies are rarely done. It would be very expensive and difficult research in terms of sample size and duration, just to show ‘that little’ difference.

Apparently, those who believe in RARP as ‘the way to go’ are less willing to believe that, in practice, the difference in the overall outcome of care might be ‘that little’, simply because the outcome depends on many factors²⁰ not just on the very surgical instrument. An interesting analogy made by a urological oncologist is taken from a consumer-centric health information website. It is entitled ‘Reality and the Robot’ and can best summarise this part:

[R]obotic surgery doesn't seem to offer much of an

¹⁹ A multinational non-profit institution that helps improve policy and decision making through research and analysis.

²⁰ One can even think of some distant but not trivial factors such as the personal character of the surgeon or whether (s)he is tired or not when operating.

advantage over standard prostatectomy. And yet, the urology community has largely adopted this as "the future". Older urologists feel they are being left behind if they don't use the robot. Younger ones are certain that their outcomes are better. Sometimes technology leads to terrific advances. At other times, it is simply a new way of doing the same old thing with different tools. You can use a hand wrench or an air-powered wrench to tighten the lug-nuts on your car's wheels. Either way, the wheel should stay on if done correctly. It won't stay on any better with one versus the other. (Source: www.RevolutionHealth.com)

4. CONCLUDING REMARKS

4.a. Key features of the sense of need

The case study of RARP has revealed various processes that provide insight into the question of why the stakeholders want this high-tech new form of care. The sense of need for RARP is formed by the stakeholders' perceptions of the benefits of da Vinci robot. The (sense of) need that has been constructed has the five following interrelated features:

- A 'self-reproducing' process*** The perceived benefits of RARP are associated with all sorts of positive notions: the pursuit of technological advancement, the desire to provide the best clinical care, competition and prestige, patients' satisfaction, passion for further innovation, knowledge production, and scientific (research) career. These features are all interdependent and reinforce one another. They are constantly circulated and reproduced via interconnections between stakeholders, due to manufacturer's promotions (to both professionals and the public), and due to mainstream image-building by the mass media. The constant reinforcement of such persuasive communication propagates the sense of need among the entire network of stakeholders and sustains a powerful flow of need for the da Vinci system. It not only shapes the sense of need but also feeds it further. A striking feature of the need for RARP is, therefore, its self-reproducing nature.
- Inevitability*** Another feature of the sense of need within the context of care delivery is the conceptualisation that using the da Vinci device is 'the way to go'. While adopting RARP actually involves a choice, the enthusiasm of stakeholders brings about a 'pressure'; a marked sense of inevitability in demanding RARP. This mindset leaves little room for any further hesitation by potential adopters and/or patients.
- Emotions*** The concepts of progress, prestige, precision, and pioneering associated with the da Vinci surgery appeal to the deeply-felt longings of those faced with the choice of purchasing the apparatus, working with it, or undergoing surgery with it. These are the same concepts that ensure convergence of motives among the stakeholders. They may stimulate the emotional aspect of the sense of need, especially if mediated by mass media or manipulated by extremely professionalised promotional endeavours. This emotional aspect implicitly exerts influence on stakeholders' decision-making in implementing RARP, thereby fuelling the sense of need. To that end, stakeholders rationalise (cognitively replace, articulate and defend) what they 'want' as what they 'need'. In other words, the attractiveness (partly) speaks for effectiveness.

Optimism (versus realism)

As the expected benefits of RARP are reproduced and reinforced among stakeholders, a shared optimistic view (on the superiority) of the therapy will dominate. This view counteracts a more realistic weighing up of the benefits of RARP in terms of the final outcome and the net added values for an individual hospital, surgeon, or patient. Optimism takes the place of realism in decision-making. It is usually not until after the robot has been purchased or after patients have been operated on by it that some (though by no means all) stakeholders may come to realise the relevance of aspects that had previously been ignored such as uncertainty over long-term clinical results, financial consequences of acquisition, capacity issues at a regional or national level, the foregone opportunity of investing in other forms of care, the accurate estimation of patient stream, and stringent judgment about who is eligible for robot surgery.

Tendency for ever-more use

Within the context of care delivery, the da Vinci system offers users the capacity to increase not only their therapeutic productivity (state of the art surgery) but also their scientific (clinical research), technical (device development) and economic (profit/status) productivity. Once stakeholders conceptualise the benefits of RARP in this way, they are inclined to demand and use the da Vinci system with a growing frequency. A tendency to 'do more' (perform ever-more operations) is also associated with a perceived pressure to perform better than the competition.

4.b. Influencing demand via package management

Potential risks

The above-mentioned processes reinforce the sense of need for the da Vinci robot. Similar self-sustaining processes probably also exist with other new high-tech forms of care. There is the risk that insufficient discerning attention is being paid to the added value of innovations. Failing to counterbalance this will drive up health care costs as well as hampering optimal utilisation of collective resources. In particular, there may be the risk of service overuse (overtreatment) and misallocation of capacity by oversupplying some services and undersupplying others (for instance, excessive technologisation of curative care because it is more profitable or prestigious). In as far as the care is part of the benefits package, the costs are largely at the expense of the social health insurance and thus borne by citizens. These potential risks emphasise the role of package management in regulating demand by influencing the sense of need.

Influencing the sense of need

Part of the regulatory capacity of package management may come into effect by influencing the incentives of stakeholders

that fuel the growing perception of need. For instance, a package manager could require establishing a mandatory national and/or multinational data registry of the outcome of different treatment methods in order to be able to obtain evidence-based verification of the real additional benefits of a technological innovation. This could avoid exaggerated assumptions being made about the benefits of technological innovations. Furthermore, a package manager could communicate with the stakeholders about concerns at a macro- (collective) level. Often, the perspective of stakeholders in implementing a technological innovation like the da Vinci system is linked to such issues as progress, prestige, precision, and pioneering. Package management, however, endorses a different set of concerns, such as allocating a limited national budget, optimising health gains for the money spent, assurance of societal benefits of health care innovations in the long run, as well as maintaining solidarity and social justice. These are often not the immediate concerns of the stakeholders in realising or requesting innovations. By signalling issues such as over-supply and/or over-treatment, a package manager can make stakeholders aware of the consequences to society in terms of the costs of health care and health insurance (premiums). In this way, the package manager will be able to enhance stakeholders' accountability to utilise innovative health care services more properly. This is what CVZ refers to as *Appropriate Use of Services (Gepast Gebruik)*.

The question here is: how can package management best influence the sense of need when it is largely constructed during the experimental period (by the early adopters) or even before implementation? (See also annex b.) In order to regulate the demand, communication with the stakeholders should take place immediately at the initial emergence of new forms of care. An explanation is given by Faulkner (2009). In the early phase of emergence, the technology itself is flexible and can be altered relatively easily, though at this point its social implications are difficult to discern. At a later stage, when the social implications become better known, it has become more rigid and it is difficult to intervene.

Benefits package management, when used as a regulatory instrument, is not intended to slow down innovation and enterprise in health care. On the contrary by its very nature, it facilitates diffusion of innovations, their broader utilization, and their further (incremental) developments. Influencing the sense of need by means of package management may have an important impact. It may ensure meeting a realistic demand whilst optimising the health gains for the Euros spent by the Social Health Insurance system. However, perhaps the latter is also a 'no-brainer'.

5. ANNEXES

5.a. Financing flow of hospital care in the Netherlands²¹

Generally speaking, the financing coverage of curative care in the Netherlands is based on a DRG-like scheme called the Diagnosis-Treatment Combination system (DBC). It consists of a set of declaration codes for different forms of care, by which care-providers can claim money from insurers. The tariff for a given DBC is an average, which allows hospitals to compensate some DBCs, which cost them more than average, with others which cost less.

A proposal to create a DBC code for a new form of care usually comes from care-providers or medical association(s). It must be supported by evidence to justify the need for a new DBC code. Such a proposal is submitted to the DBC Maintenance Organisation (DBC-O) for assessment. Upon a positive decision of the DBC Maintenance Organisation, the new DBC code is identified and sent accordingly to the Dutch Healthcare Authority (NZa) for subsequent assessment in order to register the code and establish a tariff. After registration by the NZa, that form of care is eligible for provision by hospitals and it is subsequently declared based on the tariff (the declaration code) that the NZa assigns to that form of care.

Curative care can be subject to a fixed or an open price DBC. Fixed price DBCs consist of all forms of care for which market mechanisms are not feasible or possible or where there is a large risk of market failure, for instance, acute care (emergency care, trauma, burning). This segment of curative care is called the A-segment. Care in the A-segment is contracted by all insurers at a fixed price. The open price DBCs consist of other forms of care for which there is no fixed price and the price is negotiable between provider and insurer, thus subject to competition and market mechanisms. This segment of care is called the B-segment. In 2009, some 34 per cent of hospital care was declared via B-segment DBCs (DBC-O website).

The CVZ then decides whether the care described in the DBC in question is part of the benefits package. A positive decision from CVZ means reimbursement of the requested DBC code via the collective health insurance. In order to facilitate the process for health insurers (to identify whether the claimed DBC is part of the benefits package or not), the reimbursement status of the care provided in a DBC is expressed via the colour of the DBC:

²¹ For more elaboration, see Stolk et al. (2009).

- Red: care described in the DBC is not reimbursed via the collective fund
- Orange: care described in the DBC is reimbursed either partly or under certain conditions
- No colour: constitutes the main body of curative care, which has not been subject to CVZ's evaluation and is automatically considered eligible for reimbursement.²²

It should be noted that a negative assessment by CVZ does not preclude the provision of that care in clinical practice. It only indicates that red DBCs cannot be reimbursed via the collective sickness fund, but via any private financial arrangements such as the purchase of supplementary insurance.

When assessing proposals for new forms of care, CVZ first determines, in collaboration with the DBC-O, whether the intervention in question is considered an innovation and needs an elaborate evaluation (innovative [*innovatief*] DBC). However, most frequently, the new (element of) care is regarded as a small alteration to current practice, which means there is no indication for an elaborative assessment. This often results in a mutational [*mutati*] DBC). For instance, it can be requested with the aim of claiming a higher tariff for a more expensive intervention.

CVZ's reimbursement assessment of hospital care is not limited to the introduction of a new DBC. In practice, CVZ also receives individual requests from different stakeholders, (*vrijwillige adviesaanvraag*) such as health insurers or from the Health Insurance Complaints and Disputes Foundation (SKGZ) to assess interventions, devices, medicines, etc. This form of assessment deals mostly with certain (new) elements of care within an already established DBC. Either way, CVZ's assessment framework for reimbursement decision-making is an evidence-based assessment of a combination of medical science and medical practice according to a criterion called '*Stand van de Wetenschap en Praktijk*' (translated: Established Medical Science and Medical Practice) (CVZ 2007b).

The last step in financial flow under the Zvw is payment to insurers. Insurers obtain approximately half their income from the nominal premiums directly paid by citizens. The other half comes in from the Health Insurance Fund upon assignment by CVZ. This latter payment is subject to a risk adjustment scheme in order to ensure access to care for the citizens with a high-risk portfolio. The amount of this contribution depends on the risk profile of the insured person. It is adjusted on the basis of demographic information of insured individuals (age

²² A non-coloured DBC is often translated as green, assuming that it has been subject to assessment by CVZ. However, many of DBCs that are reimbursed as part of the benefits package have **not** been assessed by CVZ and automatically fall under the benefits package.

and gender) as well as their source of income, region of residence, and (co-)morbidity due to certain chronic diseases (see figure 18).

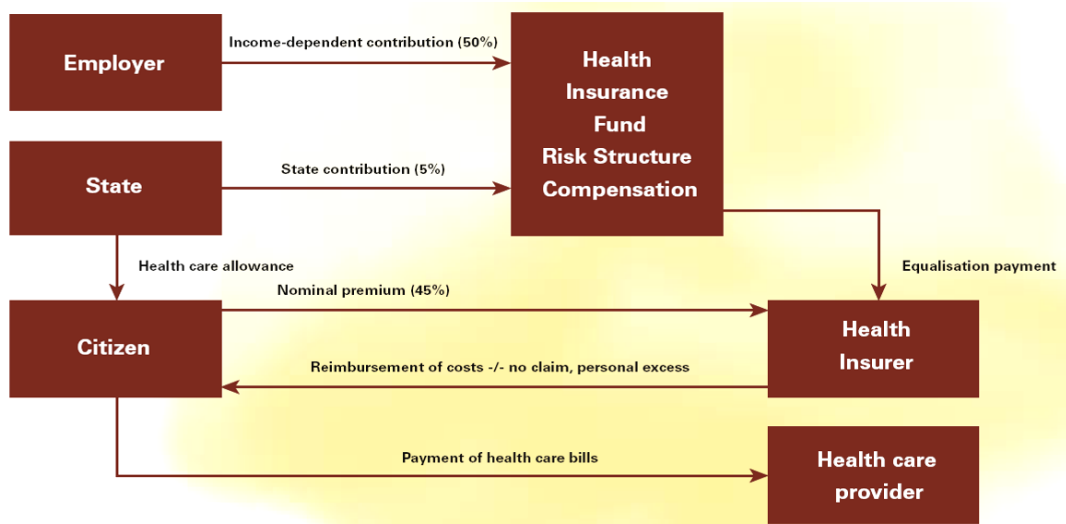


Figure 18: Financial flow under Zvw since 2006 (Source: Dutch Ministry of Health, Welfare and Sport)

5.b. Obstacles for regulating demand via package management in the Dutch context

Any reflecting on the construction of need for medical innovations as described in this report directs us to an important question: to what extent has the CVZ's task of package management been functioning as a regulatory instrument in influencing the need for medical innovations? (See also annex a.).

Within the framework of the Zvw, package management seems to have had insufficient regulatory influence on demand. Firstly, according to the Zvw, the majority of innovative forms of curative care 'automatically' fall under the benefits package as soon as they are actually used in practice. The growing perceived need for these forms of care is confronted with no reimbursing restraints whatsoever. In other words, the social health insurance system pays automatically for too many health care innovations. Of course, CVZ can at any moment decide to perform a reimbursement assessment, but such an assessment has taken place for only a few forms of (new) care. Even for these forms of care, CVZ's evaluation cannot effectively regulate the demand. In fact, when CVZ comes into picture, the need has already been established (within the context of care delivery) and the decision as to how—and how often—to implement the therapy has already been made there.

In this way, the new therapy may eventually undergo a reimbursement assessment but such an assessment lacks decent 'bargaining power' with respect to the quantity (if not the quality) of the care being involved.

Secondly, a great deal of the need for a new therapy is constructed during the experimental phase of use, on which the package manager has little influence. In fact, no exact moment can be designated at which experimenting with a new form of care is replaced by regular usage (see figure 17). During the experimental phase, the (added) benefits of the new form of care is still contingent and evolve over time but in the implementation phase, many of the benefits have already been established and the innovation has been incorporated into routine practice. From the perspective of the package manager, it is important to be able to distinguish between the experimental phase of a new treatment and the regular implementation phase because these two phases involve different sorts of regulation and financing.

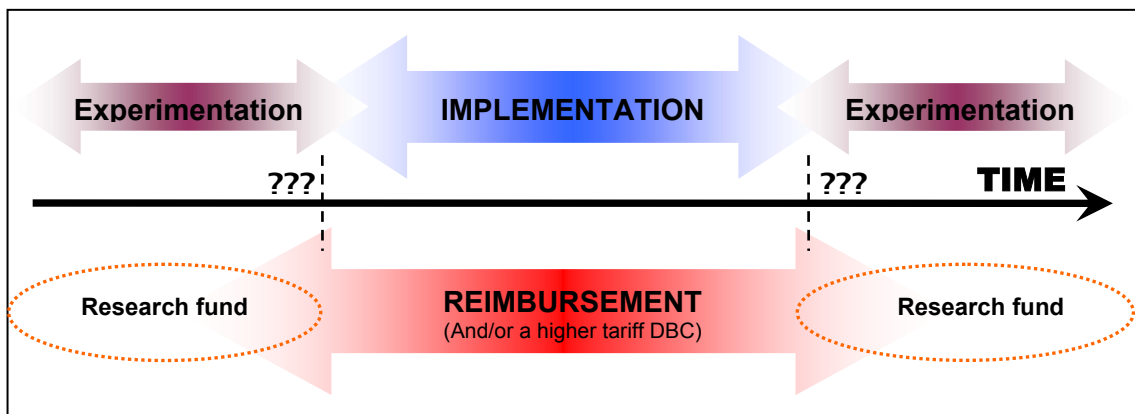


Figure 17: The unclear border between the experimental and regular use of new forms of care

In the end, it should be noted that regulatory policies on the supply-side or the demand-side which are external to the package management may not be suitable for regulating the trend of a growing perceived need. For instance, supply-side regulation by means of centralising provision of the RARP is recommended in the literature (Camberlin et al. 2009). However, the respondents of this study frequently reported the difficulty of achieving this. Likewise, policies for price regulation (such as a shift from the A- to the B-segment of care which allows price negotiation between insurers and providers) may not sufficiently influence the sense of need. In fact, reimbursing as part of the benefits package causes demand to be relatively insensitive to price unless the insurer's countervailing power is effectively in place (Grandfils 2008).

5.c. The profile of the patients interviewed

Patient	Age at operation	Year of operation	PSA test at the time of operation	Tumour stage	Method of operation	Waiting time	Gleason Score
P1	61	2006	9.7	T2	LRP	Unknown	7 (4+3)
P2	68	2005	Up to 30	T2	LRP	unknown	5 (2+3)
P3	61	2007	4.8	Unknown	RARP	2 weeks	7
P4	75	2008	8.2	Unknown	RARP	5 weeks	Unknown

5.d. Guideline for oncological care/prostate cancer

- Low risk: T1c-T2a, Gleason score <7, iPSA <10 ng/mL
- Moderate risk: T2b-c, or Gleason score =7, or iPSA 10-20 ng/mL (with two unfavourable factors: high risk)
- High risk: T3, or Gleason score >7, or iPSA >20 ng/mL (one or more factors).

(Source: <http://www.oncoline.nl/>)

5.e. Statistics of prostate operation

Sort prostatectomy	2003	2004	2005	2006	2007	2008	2009	2010
Total prostatectomy abdominal, without lymph glands	120	93	86	61	68			
Total prostatectomy perineal, without lymph glands	24	48	14	12	18			
Radical prostatectomy, abdominal	839	929	975	835	702			
Radical prostatectomy, perineal	42	68	28	17	5			
Total/radical prostatectomy, nno	443	518	382	427	439			
Total and radical prostatectomy	1468	1656	1485	1352	1232	1040	1194	1157

Number of total and radical prostatectomy operations in the Netherlands 2003-2007 (Source: Prismant website)

6. LIST OF ABBREVIATIONS

CVZ	<i>College voor zorgverzekeringen</i> [Dutch Health Care Insurance Board]
DBC-O	<i>Stichting Diagnose Behandeling Combinatie Onderhoud</i> [DBC (DRG-like) Maintenance Organisation]
EAU	European Association of Urology
EU	European Union
FDA	Food and Drug Administration
HIFU	High Intensity Focused Ultrasound
HSR	Health Services Research
HTA	Health Technology Assessment
LRP	Laparoscopic Radical Prostatectomy
MIS	Minimally Invasive Surgery
NvU	<i>Nederlandse Vereniging voor Urologie</i> [Dutch Association of Urology]
NZa	<i>Nederlandse Zorgautoriteit</i> [Dutch Healthcare Authority]
OR	[Surgical] Operating Room
ORP	Open Radical Prostatectomy
PET	Positron Emission Tomography
PSA	Prostate-Specific Antigen
RARP	Robot-Assisted Radical Prostatectomy
RIVM	<i>Rijksinstituut voor Volksgezondheid en Milieu</i> [National Institute for Public Health and the Environment]
SKGZ	<i>Stichting Klachten en Geschillen Zorgverzekeringen</i> [Health Insurance Complaints and Disputes Foundation]
STS	Science and Technology Studies
ZN	<i>Zorgverzekeraars Nederland</i> [Sector Organisation Representing Private Health Care Insurers]
Zvw	<i>Zorgverzekeringswet</i> [Health Insurance Act]

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