INCREASING THE SAFETY OF USE OF MEDICAL DEVICES BY IMPROVING PROCUREMENTS

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Delft, Monday, November 30, 2009

Master thesis report

Master Engineering and Policy Analysis
Faculty Technology, Policy and Management
Delft University of Technology
INCREASING THE SAFETY OF USE OF MEDICAL DEVICES
BY IMPROVING PROCUREMENTS

Delft, Monday, November 30, 2009

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SUMMARY

The healthcare sector in the Netherlands is changing on two aspects. The first aspect is a change from a planned healthcare sector towards a more market organised healthcare sector. The policies in the planned healthcare sector failed to stop the annual rising costs. Therefore the Dutch government decided to organize the healthcare sector more competitive. The second change is a worldwide trend aimed at improving the safety of patients. At the end of the 20th century it was proven that incidents in the healthcare system of the USA caused more deaths than traffic did in the USA\(^1\). In the Netherlands each year about 1,700 people die from a preventable incident, while another 30,000 suffer from a preventable incident\(^2\).

Both changes are real for Dutch hospitals, which are currently putting all their efforts in adapting to the changes. This research focuses on procurements of medical devices by academic hospitals. Medical devices have a direct relation with safety of patients and with a competitive healthcare market. An academic hospital is studied in depth to discover what problems are experienced with procurements. The executive board of the hospital, the problem owner of this research, discovered that the current procurement process is not supporting the procurement of safe medical devices. Improving the procurement process requires attention for the wishes of the executive core, as their benevolence to share knowledge and to use the method are required for a procurements that increase safety during use. The problem formulation for this research is:

_How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?_

The problem definition is broad and required a specification of areas that required improvement. This was researched with an in dept investigation of what can be seen as a qualitative good procurement with a desk research and a description of the current way procurements are carried out with 19 interviews. Three parts needed to be improved:

1. The regulation how experts are involved in the procurement process is not based on risks
2. The regulation that indicates how the selection of suppliers should be carried out is not in use
3. A risk analysis for a medical device is going to be procured is not described in regulation

The first point is further researched, as that is the key for solving the other two problems as well. Without involving the right experts, it is not possible to perform a good selection between suppliers or a useful risk analysis. The focus is on the governance of the experts. The solution is bounded by the precondition that it may not create dysfunctional bureaucracy that consumes time from the core process of healing patients, in order to be acceptable for the executive core. This creates a trade off between procurement quality and procurement costs. Therefore a framework for adaptive involvement of experts is chosen as the solution to this problem, with the

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\(^1\) (IOM, 2000)

\(^2\) (Wagner & de Bruijne, 2007)
thought that the more risks are possibly introduced by a medical device, the higher the quality of the procurement should be.

This framework requires the development of indicators of required procurement quality, means to achieve a procurement quality, and a system that selects the appropriate procurement quality. Quality becomes the measure in which safe use of a device is made possible with the procurement.

The indicators were identified with a causal relation diagram. With use of three selection criteria a total of 8 factors were identified to be useful as indicators for the procurement quality. To indicate the possibilities to increase the procurement quality an end-means diagram was constructed that links all the possible means to the end, which is improving the procurement quality.

For each indicative factor a bandwidth of its possible score is given. This bandwidth is used with a gradual scoring system to provide a score of risk on adverse incidents for a medical device that is planned to be procured. The decision makers in the hospital should adapt the weights in the scoring system so that it represents their preferences.

The risk score indicates requirements on the procurement quality. In this research the score is used to determine the form of the procurement team and its supervision. That is a part of the procurement quality. For both the procurement team and for the supervision the different forms are identified using three dimensions, which differ between procurement team and supervision. The value of a dimension increases whenever the potential risk a device poses increases. The general principle is that the higher the risk is, the more experts should be in the procurement team and the higher the governance level should be for the supervision team. This creates a system in which high risks are countered by knowledgeable procurement teams that are supervised by staff that is close to the executive board, who in the end is responsible for safety in the hospital. This is shown in the final framework below.

A framework that connects the procurement form with the risk level during use

<table>
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<tr>
<th>Risk during use</th>
<th>Procurement team</th>
<th>Supervision team</th>
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<td></td>
<td>Formation</td>
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<td>Team + advice</td>
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ACKNOWLEDGEMENTS

This report is the result of my graduation research for the Master Engineering and Policy Analysis (EPA), carried out between March and November 2009. In this research the procurements of medical devices in the LUMC are studied, as a part of a broader study on how to improve safety and efficiency throughout the whole life cycle of medical devices.

During this graduation project I discovered that the social implications of engineering efforts are much harder to research than expected. The social problems tend to be the opposite of technical problems; open, ambiguous, subjective, political and changing in time. This is something we learn by heart in the EPA program, but it is an entirely different experience to deal with in practice. In the end this was the most educative project I carried out during my education.

This graduation project does not only reflect my efforts, but also that of many others who helped and supported me during the research. First I want to thank my graduation commission. Floor, thanks for inviting me to join a project within the LUMC, and for taking the challenge to supervise a student that has a different expertise than you have. It resulted in a lot of fruitful discussion. Alexander, thanks for the endless support during my quest for a graduation topic on healthcare, the supervision during this graduation project and for expressing the real value of doing something that is exiting to do. Wil, thanks for your essential guiding comments and helpful advice when the presentation of research findings required changes. And Rob, thanks for becoming a member of the committee, although your time is very limited. Your comments during our meetings were very helpful.

I am grateful to the working group of the LUMC for the discussions during the meetings. A special thanks goes out to Thera and Rob, who provided me with the opportunity to do research in the hospital. I really appreciate the possibility to discover a hospital from the inside.

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Of course I want to thank all my friends from my hometown, from Rotterdam and from Delft, for always being supportive, providing a listening ear and being the essential distraction. I really appreciate the fact that we are discovering our own place in the world together.

I am very grateful to my family, especially my parents. Thanks for your support in the good times and in the bad times and for stimulating me to continue studying. In the end I am very glad with that choice, and I hope you think alike.

Anouk, you were the success factor for me to get my Master degree, for which I am endless grateful to you. Thanks for making our study time a great time. Thanks for trying to change me in an optimist, instead of a realist, although it is still al long way to go... And I am really exited to face our future together! Let’s hope the time in Delft provides us with many possibilities to live our dreams.

Sander van der Wiel,  29 November, 2009
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<td>Dutch</td>
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<tr>
<td>CMC</td>
<td>Central Materials Committee</td>
<td>Centrale Materialen Commissie</td>
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<td>CSD</td>
<td>Central Sterility Service</td>
<td>Centrale Steriliteits Dienst</td>
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<td>DBC</td>
<td>Diagnose Treatment Combination</td>
<td>Diagnose Behandeling Combinatie</td>
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<td>HRM</td>
<td>Human resource Management</td>
<td>Personeel en Organisatie</td>
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<td>IC</td>
<td>Intensive Care</td>
<td>Intensieve Zorg</td>
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<td>IGZ</td>
<td>Netherlands Healthcare Inspectorate</td>
<td>Inspectie van de Gezondheidszorg</td>
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<td>Inspectorate</td>
<td>See IGZ</td>
<td>Zie IGZ</td>
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<tr>
<td>INK</td>
<td>Institute Dutch Quality</td>
<td>Instituut Nederlands Kwaliteit</td>
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<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
<td>Instituut voor Geneeskunde (USA)</td>
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<tr>
<td>LEVV</td>
<td>National Expert centre Nursing and Care</td>
<td>Landelijk Expertisecentrum Verpleging en Verzorging</td>
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<td>LUMC</td>
<td>Leiden University Medical Center</td>
<td>Leids Universitair Medisch Centrum</td>
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<td>MDD</td>
<td>Medical Device Directive</td>
<td>Besluit Medische Hulpmiddelen</td>
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<td>MinOCW</td>
<td>Ministry of Education, Culture and Science</td>
<td>Ministerie van Onderwijs, Cultuur en Wetenschap</td>
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<td>MinVWS</td>
<td>Ministry of Health, Welfare and Sport</td>
<td>Ministerie van Volksgezondheid, Welzijn en Sport</td>
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<td>NIAZ</td>
<td>Dutch Institute for Accreditation in Healthcare</td>
<td>Nederlands Instituut voor Acreditatie in de Zorg</td>
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<td>NVZ</td>
<td>NVZ Dutch Hospitals Association</td>
<td>NVZ Vereniging van Ziekenhuizen</td>
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<td>OMS</td>
<td>Order of Dutch Specialists</td>
<td>Orde van Medisch Specialisten</td>
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<tr>
<td>PACS</td>
<td>Picture Archive and Communication System</td>
<td>Foto Opslag- en Verspreidingssysteem</td>
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<tr>
<td>RIVM</td>
<td>The National Institute for Public Health and the Environment</td>
<td>Rijksinstituut voor Volksgezondheid en Milieu</td>
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<td>VAZ</td>
<td>Association for pharmacist's assistants in Hospitals</td>
<td>Vereniging van Apothekersassistenten in Ziekenhuizen</td>
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<tr>
<td>VGM</td>
<td>Safety, Health and Environment department</td>
<td>Veiligheid, Gezondheid en Milieu departement</td>
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<tr>
<td>WIBAZ</td>
<td>Working group Instrumentation Governance Academic Hospitals</td>
<td>Werkgroep Instrumentatie Beheer Academische Ziekenhuizen</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
<td>Wereld Gezondheidsorganisatie</td>
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<tr>
<td>ZIS</td>
<td>Hospital Information System</td>
<td>Ziekenhuis Informatie Systeem</td>
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Medical devices have become essential tools for the healthcare sector to perform its work. In the past century huge improvements are made in diagnostic and curing possibilities thanks to medical devices, both in quality and in quality. The developments in this century show a displacement of medical devices from the hospital into our homes, and even our bodies. These developments require a high level of communication between devices to bring all the information where it is needed and in the right form.

For hospitals this ongoing innovation in the medical device industry provides new and improved possibilities to cure their patient, while at the same time they should understand the newest developments so to avoid misuse. This research studies the procurements for medical devices in the LUMC (Leiden University Medical Center - Leids Universitair Medisch Centrum). It aims to improve the safety of patients and staff who come in contact with medical devices, by improving the procurement of medical devices.

In this chapter a description of the organisation of the hospital is provided in § 1.1. This describes the position of the problem owner, the organisational goals, resources, output, organisation type and the regulatory context. § 1.2 presents the external ongoing changes that are relevant for this research. These are important changes for the hospital, as it will influence the way care is provided to patients. In § 1.3 the problem for the problem owner is identified. This is summarized in a problem definition, which is used throughout this report as a reference to the problem. The problem definition is focused on procurements.

In § 1.4 a conceptual diagram about the life cycle of medical devices in a hospital is developed. The life cycle diagram explains to the reader what a procurement is, and what its function is in relation with the other phases of the life cycle. The research is delineated in § 1.5 by boundaries, so to create a working space for this research. With the research boundaries and the problem definition it is possible to start formulating research questions in § 1.6. The questions will guide this research. The approaches and methods that are used to answer these research questions are described in § 1.7. The outline of the report is given in § 1.8. Now first an overview of the LUMC is presented.

§ 1.1 The LUMC

This paragraph provides an overview of the organisation that is researched. It discusses the position in the healthcare sector, its main goals and targets, a resource profile, the organisation type and the problem owner.

§ 1.1.1 Position in the Dutch healthcare system

In the Dutch healthcare system three levels of care can be distinguished. The first level of care (eerstelijnszorg) is provided close to home, and is meant to treat not too serious complaints. General practitioners, first level psychologists, dieticians and physiotherapists are examples of first level care institutions. If no adequate treatment can be provided by first level care institutions, they will refer a patient to a second or third level care institution. Hospitals provide second level care (tweedelijnszorg). They provide treatments for most common complaints of the population.

If a patient cannot be treated in a second level care institute they will be referred to a third level care (derdelijnszorg) institute, which are amongst others academic hospitals. Third level care is for patients who have rare complaints, hard to diagnose complaints or complaints that are hard to treat successfully. The LUMC is an academic hospital and provides second and third level care. It provides the second level
care for the region it is located in. It provides the more rare third level care for the super regional and national level.

§ 1.1.2 Goals and means

![Diagram](figure 1.1)

**Legend:**
- High level goal
- Lower level goal
- Operational target

The motto used in the mission statement of the LUMC is “be Better become Better” or in Dutch “Beter zijn Beter Worden”. The LUMC sees itself as a “Centre of Medical Improvement”. Both indicate a goal that is aimed at improving quality by means of innovation.

In the mission statement (LUMC, 2009c), the LUMC defines its primary goal to be the continuous improvement of the core businesses to the highest possible level. As an academic hospital, it is a highly integrated cooperation of a university, a hospital and a research centre.

The core business of the university part is education of medicine and biomedical students and postgraduates. The classes are given in the LUMC and for the practical experience it works together with other hospitals in the region. The core business of the hospital part is patient care with a focus on top clinical (topklinisch) and top expertise (topreferente) care. The LUMC also delivers second level, but explicitly chooses to limit the quantity of it. The regular hospitals in the region are well capable of providing second level care. The core business of the research part is to improve healthcare by the interaction of clinical and fundamental research (LUMC, 2009c).

These three core businesses are made into goals in figure 1.1. Together with the highest goal, they form the high level goals. High level goals will hardly change in the future, as it represents the core goals and reasons to exist of an organisation.

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3 Top clinical and top expertise care can be seen as subgroups of third level care.
Chapter 1  Research definition

The lower level goals are specified in the ‘strategic plan 2009-2013’ (LUMC, 2009d). The strategic goals are determined for the three core businesses of the LUMC; education, specialized care and research. The lower level goals are presented in figure 1.1. The argumentation of this goal tree can be found in Appendix A.

This research will support two low level goals: ‘Improve medical technical quality’ and ‘Improve care quality for patients’. Both are part of the high level goal ‘higher quality of specialized care’. Therefore the goal of this research project will in the end be to increase the quality of specialized care of the LUMC.

§ 1.1.3 Resources and results

The result that is achieved for the goals described in the above paragraph depends on the resources that are available to the LUMC, and how these resources are spent. That is visualized in figure 1.2. The information comes from the annual report for 2008 of the LUMC (2009b).

In the block fund origin, it is shown that the origin of the function centred accounting is the old healthcare system and both DBC funds have their origin in the new healthcare system. This is the result of a financial change from the supply driven financing towards demand driven financing. Especially academic hospitals are slower in adapting to the new financial system, because a large part of their activities are not part of financially standardized diagnoses treatment combinations, called DBCs.

\[\text{figure 1.2 fund origin and distribution and results}\]

§ 1.1.4 Organisation

For the organisation chart, please see figure B.2.

The executive board governs the LUMC. The board is supervised by the supervisory board and is supported by several staff organisations, for administration and finance, research, human resources,
communication and planning and control. Besides the staff organisations that support the executive board, there are also staff organisations that assist the five medical divisions in their activities. These are facilitating services (please see figure B.3), Information and Communication Technology (ICT) and Safety, Health and Environment (part of human resources).

Five different division management teams govern the five divisions. The management teams govern the operations of the different departments within each division. For more details on what departments are in which division, please see figure B.2.

A so-called chef de clinique (daily responsibility) and a department head (end responsible person) govern a department. Both are medical specialists who at the same time manage a department. These departments, headed by medical specialists are specialized on a certain field, for example cardiology or urology.

The governmental philosophy is described in the strategic plan (2009d). The board is end responsible for educational, healthcare and research activities. The LUMC has an integral management with local operational governance by the division management team. Integral management means that one central authority, the board, controls the budget. The board distributes the budget based on the mission statement and strategic goals (result driven) confronted with the departmental historical needs and motivated requests (process and research driven). Integral management furthermore means that the board is responsible for all that exceeds the divisions. The quality of the delivered healthcare is part of that.

The local operational governance of divisions gives a great deal of responsibility to the management teams of the different divisions. They are responsible for the budget they are granted with, the process quality of the core business and personnel quality and quantity.

In the book *Structures in fives: designing effective organisations*, Mintzberg (1992) repeatedly uses hospitals and education centres as the classic examples of organisations he refers to as a professional bureaucracy. In general, most service industries with complex but similar problems are organized as professional bureaucracies. In Appendix C it is determined if the LUMC has the characteristics Mintzberg has given to professional organisations. It is concluded that all four main characteristics are indeed also possessed by the LUMC, therefore, the organisation of the LUMC can be called a professional bureaucracy. The four characteristics are:

1. Primary coordination mechanism of work is by standardization of skills
2. The most important part of the organisation is the executive core
3. The design of the organization is characterized by horizontal and vertical decentralization, as well as horizontal specialisation and training
4. The situational factors of importance are; complex but stable environment, not a high technology sector, subject to trends and little regulation

Mintzberg has recognized three main complications for the governance of a professional bureaucracy. These are all three results of the autonomy of the expert. These complications are also likely to be existent within the LUMC. The three complications are elaborated in § C.2 and are:

1. Multi-issue problems require coordination that is not present
2. Experts are hard to control
3. Multi-disciplinary innovations are hard to accomplish
The executive board of the LUMC has indeed the same problems, as is recognized in the strategic plan. These problems are (LUMC, 2009d, p. 20): The organisation has a lot of bureaucracy, there is incapacity to point another on undesirable behaviour, personnel is not costs aware and the different divisions and departments create restrictions in services that require input of more than one department. Furthermore is it stated in the strategic plan that the local management structure leads to less decision power for changes relevant for the whole organisation. To overcome these difficulties Mintzberg has provided a review of effectiveness of solutions, which is presented in § C.3. The organisation difficulties are not the focus in this research, but it is an important contextual issue that has to be kept in mind when reading this report.

§ 1.1.5 The problem owner

This research is concerned with the procurement of medical devices. The policies for procurements exceed the division responsibilities for two reasons. First, the LUMC strives for a uniform procurement approach. Second, there are procurements imaginable that are made for the whole hospital. Examples can be the procurement of beds, syringes or bandages.

As is explained in the previous subparagraph, the integral management approach defined by the executive board states that the board is responsible for all that exceeds the divisions. The problem owner for this report then becomes the executive board of the LUMC. The executive board in the end is also responsible for the quality of healthcare, of which safety is a derivative this will be explained in more detail in § 1.3.2 and Chapter 2.

§ 1.2 Ongoing changes for the problem owner

The last paragraph gave an overview of the LUMC, on aspects of goals, strategies, resources and outcome and organisational type. This paragraph presents two relevant changes that are ongoing for the problem owner. The first change is a management change towards a quality-based management in the healthcare sector. Quality management is a hot topic in the healthcare sector since it was found that hospitals cause more preventable deaths than the Dutch road transport causes. The second change is one technology change towards integration and communication of medical devices. It is likely that in the future medical devices will be surround us all the time, also outside hospitals.

§ 1.2.1 Quality management

Adverse event research

In 2000, the medical world and government departments organizing healthcare were shocked by the report To Err is Human of the Institute of Medicine. In the book it is concluded that between 44,000 – 98,000 people died per year by avoidable adverse events in U.S.A. hospitals (IOM, 2000). If those numbers are extrapolated to the Netherlands, that would mean an avoidable dead toll of 1500 – 6000 people each year (IGZ, 2000), more than by traffic accidents and unacceptable for the Dutch society.

A Dutch quantitative research showed that the extrapolation was right. Of all hospitalized persons (1.3 million) in the Netherlands, about 3% passed away in the hospital, which are about 42,000 patients. Of this group, 4.1% (± 0.7%, 95% CI) or 1,735 experienced an adverse that can be related with the premature death. Next to premature deaths, in total 2.3% (± 0.4%, 95% CI) of all hospitalized Dutch
persons experienced a preventable adverse event, which are about 30,000 patients. (Wagner & de Bruijne, 2007).

These are shocking numbers that are seen as unacceptable, which made all that are involved in healthcare aware of the need to improve the quality of care drastically.

**Regulation to counter preventable adverse events**

In 1996, the Quality Law for Healthcare Providers (Kwaliteitswet Zorginstellingen) replaced a system that regulated how healthcare should be organized and provided, by a system that prescribed what should be organized. Healthcare providers could now organize with their own vision how they would meet the prescribed quality norms. The Quality Law demands that healthcare providers deliver justifiable services, conduct a conscious quality policy, use a quality management system and make yearly quality reports for internal use. Furthermore should they improve their quality and the quality management system by making changes that are based on measured outcomes.

The Ministry of Health wants the representative groups of the specific types of healthcare providers to define and elaborate the term justifiable services and conscious quality policy explicitly, together with health insurers and patient organisations. Furthermore should they design and implement their own quality systems. Thus, the Quality Law demands self-regulation of the healthcare providers in order to come to a high quality health care system. But the implementation speed of the quality management system by hospitals is not as swift as the government had hoped for (IGZ, 2000).

In 2000 the IGZ (Netherlands Healthcare Inspectorate - Inspectie van de Gezondheidszorg) decided to shift its oversight focus to the fast introduction of quality management systems. The primary reasons was the shocking number of preventable deaths named in the IOM report of 2000, named above. The believe of the IGZ is that a focus on quality within healthcare organisations will lower the number of preventable adverse events. A vast amount of reports were published by the IGZ about quality management in healthcare organisations. In total 4 reports were published that reacted on the current state of the use of quality management systems for medical devices in hospitals, in 2002, 2004, 2005 and 2008. The message in the reports was that the Inspectorate was not satisfied with the progress of the introduction of quality management systems for medical devices, that the present systems are not adequate for managing medical devices and that responsibility for all this lies at the hospital boards and specialists, as they are responsible for the safety of patients. For more details and background information, please see § E.1. With these reports it was made clear what the implications of the Quality law on healthcare providers in general and hospitals specific is. It means healthcare providers themselves are responsible to design and introduce quality management systems, as they are the most capable and knowledgably group. At the same time they were not on schedule with the introduction of these systems.

**Safety management system in practice**

What is improved with the quality management system depends on the definition of quality. From Quality Law for Healthcare Providers it is demanded that healthcare providers themselves define what quality is. For a hospital one can think of the processes surrounding the patient (adverse events, waiting times, satisfaction), patient-staff interaction (experienced friendliness, complains), staff (education level, turnover, pressure), devices (incidental maintenance, user mistakes) building (room space, storage space, ventilation quality) and governmental factors (financial results, image to society, image to professionals, satisfaction of staff). In general three subclasses of quality are used by professional
organisations in healthcare, which are safety, efficiency and patient assistance. In this report the focus is on safety. So that will be the key issue whenever quality is discussed.

Several professional organisations in healthcare have stated what should be part of a safety management system in a national agreement, the NTA 8009:2007. Not the whole agreement is presented, only the general idea. The core of the system contains three parts:

1. At the core of the safety management system is a clear and dedicated leadership of the management teams and the executive board to improve safety.
2. This is supported by a clear definition of tasks and responsibilities of the employees, who should be trained and experienced in working with risks. Furthermore a safety culture should be present in the whole hospital.
3. The last demand for the core of the safety management system is a clear and open communication between employees, management and patients, about risks, responsibilities and mistakes.

The core of the safety management system is involved in all four phases of the so-called improvement cycle; plan, do, check and act. For each phase different parts are of importance.

- For the Plan phase, especially the executive board is responsible for the implementation of a safety management system and its improvements from the act phase. The management level is responsible for the practical planning of the whole system, the executive board for facilitating planning possibilities.
- For the Do phase, parts as the patient participation, prospective risk analysis, operational control measures and management and governance of changes are important to specify during the act phase.
- And when actually doing that what is planned, a constant flow of information is needed about the operational processes. This is the Check phase of the improvement cycle. Especially incident reporting, retrospective risk analysis and monitoring reports are important parts that are defined in the NTA 8009:2007.
- All the information that is gathered during the check phase is used in the Act phase to improve the operational processes. This phase also is the start of the safety management system when that is not yet present. For the act phase the management is responsible for establishing (research) groups that improve and communicate why and how a specific improvement should be implemented.

The description of the safety management system is on a high level for every aspect within the hospital. The more practical implications for the complete life cycle of medical devices in a hospital is explained in the 2 guides of the NVZ (Dutch Organisation of Hospitals - Nederlandse Vereniging van Ziekenhuizen), published in 2004 and 2007. The first guide gave a reaction on the specific complains of the IGZ report of 2002. It provided hospitals with 7 measures to be taken in order to solve the complains of the IGZ. As these complains were not concerned with procurements, it is not solved either with the 2004 report.

In the report of the NVZ (2007) called Practical guide Risk Management and Medical technology (Praktijkgids Risicomanagement en Medische technologie), a detailed guideline is provided how the

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4 Amongst others the NVZ, OMS and LEVV. For a complete list please see NTA 8009:2007, p. 14
5 This research investigates how procurements of medical devices can be improved so to increase the safety of use of these devices. It is thus part of the plan phase of the improvement cycle.
management of medical devices in hospitals can be placed in an improvement cycle as demanded by the Quality Law. The main focus of the report is on the safety of use, prospective and reactive risk analyses techniques and the maintenance frequency and procedures. The NVZ refers to a report of the NVKF (Dutch association of clinical physicists - Nederlandse Vereniging van Klinische Fysica) for more information about procurements. This guide actually (NVKF, 2007) does not provide practical guidelines, but mere requirements on the processes in the hospital. The detailed and practical description how these requirements for procurements for medical devices can be met is not available in literature of the professional groups, or in research publications.

There is a change in the healthcare sector towards a higher quality of care. This is needed for hospitals to comply with the law, but also to compete with another. More and more there are reports and indicators to compare hospitals with another, on aspects of safety, efficiency and patient assistance. As there is no practical guide present what a safety management system for medical devices should look like, the hospitals have to develop it by themselves.

**Adverse event research related to medical devices**

A good start for developing a system is to now on what the safety management system should focus. Here a review of adverse event research is presented. In 2008 Wagner et al. published a follow up research on the report of 2007 that told how many adverse events there were. The 2008 research searched for the causes of these adverse events. It was carried out on 50 departments from 21 hospitals on three department types: internal medicine, surgery and the emergency department. The department staff was asked to report anything that did not go as it supposed to go, related to patients. This includes near adverse events, adverse events and preventable adverse events. In total 6 categories of incidents were defined. The category directly related to medical devices is ‘material and devices’. This category ended up as 2nd dominant category related to (near) incidents for the departments emergency and surgery, with 20.3% respectively 15.6% (Wagner, et al., 2008).

The category ‘material and devices’ is too wide to specify a cause of what should be improved. It does indicate that it is a category that deserves the attention the IGZ gave it over the years in several reports and conferences.

There seems to be no qualitative data present that makes clear what the root causes of incidents related to medical devices is. A systematic review of 6 hospital adverse event research papers of De Vries, Ramrattan, Smorenburg, Gouma and Boermeester (2008) made 3 classifications possible, on provider of care, location, and type of event. The former two categories have no relation with medical devices. From the category type of event, the classes were specified towards the processes of care. As these processes do not contain any details if devices were used, this also does not provide an answer what the most dominant causes are.

**Summary**

There is a shift in the healthcare sector from a supply driven towards a demand driven system. At the same time there is a strong focus on the use of quality management systems, so to lower the number of preventable adverse events. The government pushes both the shift towards demand driven healthcare provision and the focus quality, while the healthcare sector itself is responsible for the detailed design of

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6 Categories: Diagnosis and Treatment, Material and Devices, Mixed-up or Incorrect Data, Protocols and Agreements, Cooperation with doctors, Other
the solutions. These designs come from the professional organisations in the healthcare sector, who test and communicate these developments to its members.

To lower the number of adverse events, the use of a safety management system is an accepted method. This research is concerned with the procurement of medical devices, so to increase the safety during use. But for medical devices in hospitals there is not yet a safety management system designed. Hospitals themselves are now responsible to design the safety management system. A good starting point would be to know the cause of adverse events with medical devices, but there is no quantitative evidence available in the scientific literature that indicates specific causes.

§ 1.2.2 Innovations

Medical devices have provided great improvements in diagnostic capabilities and in curing possibilities and the healthcare sector more and more relies on medical devices for their procedures. The resolution, contrast and sharpness of diagnostic X-ray, Magnetic Resonance, and ultrasound are of several orders of magnitude larger than 20 years ago. Invasive tools used in the operating theatres make it possible to perform complicated surgeries, without the need to create large incisions. These days it is even possible to cure a patient without the need for surgery, while it would have been required a decade ago. Even the simple dripper system of infusion has changed into electronic pumps that precisely administer medicine with the possibility of different profiles. The intensive care is no longer the only place where real-time monitoring is in use; more and more it is used on every department. In a few years monitoring will even come to our homes (domotics), which makes it possible for doctors to see how patients are actually behaving in reality, or when help is required.

As with all high technological products, an ongoing evolution of features and improvements are added to the current medical devices. Healthcare device producer try to distinguish themselves from others by adding extra features and possibilities with every new generation. It are the healthcare providers themselves who reward these developments by buying the devices with a lot of functions in it. More and more this evolution towards more functions and improvements leads to a focus on the features. But in the end the device should be functional, effective, effective and safe to use as well. These criteria should actually be more important than functions; the functions are only the measures to achieve a certain goal, not the goal on itself.

The ongoing innovations leads to more advanced devices into the hospital. Doctors are no longer the specialists on every aspect of their work and require help of engineers to explain, maintain and sometimes explain the devices. The coming revolutions in healthcare, such as Patient File System, domotics, nanotechnology, predictive medicine and the bioengineering of organs and tissue are just a few examples of technologies which require a cooperation of different expert disciplines to master the use of it. The same is valid for the procurements of these technologies.

The future is always uncertain, but can be estimated. The forecast for the healthcare sector is that in the near future the ongoing technological evolutions and revolutions require it from the healthcare institutes to know what they require and to know what they are purchasing. Otherwise for sure resources are wasted and the number of accidents will increase.
§ 1.3 Problem definition for the problem owner

As defined in § 1.1.5, the executive board of the LUMC is seen as the problem owner in this report. This paragraph explains the main causes of the problem the executive board faces.

§ 1.3.1 Limited power to control external changes

The last paragraph explained that in the current healthcare sector there are two ongoing changes that have a large influence on how the healthcare sector works and performs; an organisational change towards a quality driven supply of healthcare services and the coming technological revolutions that have a potential to change the way the healthcare sector performs.

For the LUMC executive board these trends are impossible to control. The organisational changes are towards more quality is demanded by society itself. The healthcare providers are compared in the media, for example via annual reports of the IGZ (Prestatieindicatoren) and annual publications of Elsevier (Beste Ziekenhuizen) that compare all hospitals on many aspects. For a comparison of the best quality for specific treatments or specialisation, one can consult different websites\(^7\) that keep track of quality with ongoing enquiries. The demand for quality of healthcare also manifests itself whenever there is an incident that is seen as shocking. These incidents are extensively reported in the media. A few recent examples are the fire in the Twenteborg hospital and the chance of HIV infections as a result of a wrong washing procedure of scopes in the Bernhoven hospital. Even a television show is devoted to medical incidents\(^8\).

The technological evolutions are pushed upon hospitals by the medical industry that keeps on changing and improving their products. The revolutions are pushed upon the hospitals by the government (electronic patient file system), medical device producers (Domotics), spin-off companies of universities and universities themselves. For the board of the LUMC these changes cannot be controlled in any way, except possibly when the research is carried out in the LUMC or by a spin-off company.\(^9\)

Summarized, these changes are to be seen as external factors for the board of the LUMC.

§ 1.3.2 Need to improve internal processes

As the changes towards quality and more technology are out of the control of the LUMC board, there is a need for the board to deal with these changes in the best possible way.

This research has a focus on procurements of medical devices. Procurements are an important part for improving quality. By the procurement of a certain device that contains certain technologies, these device and its technologies are decided to be used for treatments. By procuring devices that are safer than devices that deliver similar functions, already an improvement is made for the safety of patients.

A recent procurement showed that currently the procurement of medical devices is not as it should be. In 2004, the LUMC started a procurement of syringe pumps for three of the five divisions of the LUMC. The procurement started in one division. Soon it turned out that because of the investment costs it was required to write out a European tender. The rules for a European tender required the division to look for complimentary wishes within the LUMC itself. It was found that two more divisions also needed new syringe pumps, so the project was scaled up to three divisions. The procurement started in 2004 and was expected to finish within two years. In March 2008 the first fully functional pump of a total of five hundred

\(^{7}\) For example www.independer.nl or www.kiesbeter.nl

\(^{8}\) Medische Mitters (AVRO)
was delivered to the LUMC. The last delivery arrived this year. The procurement thus took a little less than five years, while it was planned to take two years. In order to analyse what had gone wrong in the LUMC, a research was started. The report of this research identified four main reasons for the doubling of the procurement time (Koornneef, 2008) (internal LUMC report):

1. The list of requirements used for the European tender was not clear, both within the LUMC and for the suppliers.
2. The policy areas that were relevant for the functioning of the pump (medication policy, Electronic Patient File coupling with the pumps medication, Electronic Patient File introduction in LUMC) were subject of major policy changes, which were not attuned.
3. Communication with the supplier was not optimal, as the supplier had used salesmen as spokesmen towards the hospital.
4. The governance of this procurement missed clear definitions and descriptions on essential parts of the procurement, like mission, definitions, responsibilities for the different project groups, authorizations and internal communication.

Point 4 is essential for the functioning of any procurement within the LUMC, not only for the syringe pump. But it is shown that currently guidelines are missing on how a procurement should be done. This leads to a situation in which the quality of the outcome of a procurement depends solely on the complexity of the procurement and the quality of the involved personnel. For the procurement of the syringe pump it lead to a situation in which the first delivered pumps were returned to the supplier within a day, as the expected function of a bolus injection was not in line with the actual function. And even now there are complains about the pump, which have the potential to harm patients.

It can be concluded that with the current procurement processes the LUMC board does not have a method in use that improves safety for patients by only procuring devices that introduce the least amount of harm. Furthermore are the procurements not in line with what is demanded by the Quality Law. That Law demands there to be a prescribed quality system to be in use. Last, with the upcoming innovations that are described in § 1.2.2, it becomes crucial for the hospital to have an adequate procurement system in use that is able to select those innovations that are worth it to adopt and acceptable safe to use.

§ 1.3.3 Limited power to change internal system

The board should facilitate the improvements on current procurement processes. There are however three main limitations for the LUMC board to improve the current process:

1. The current knowledge about procurements is limited to only one case example, described in § 1.3.2. Without this knowledge any advice to improve the current processes may create more problems than are solved, as the problem area is not known well enough.
2. As described in § 1.1.2, there is not detailed description or a guide available from the professional organisations describes how procurements should be arranged. In general these reports are guiding the decisions of the board. Now it up to the board to decide what to implement.
3. The LUMC is an organisation that can be typed as a professional bureaucracy. In this organisational structure the experts at the bottom of the organisation have the real power, because they are the only ones that possess all knowledge to judge their own work. As described by Mintzberg (1992), the experts have a strong tendency to spent as much resources as possible on the core of what they are doing. For an academic hospital this means either research, education or
patient treatment. Any improvement to the way procurements are done is very likely to directly consume more resources. So the necessity of the improvement needs to be communicated very well by the board to the organisation in order to make a change a success.

§ 1.3.4 The problem that is faced by the problem owner

This report is a partial input to the board on point 2, named in the previous subparagraph. It provides an advice for what can be implemented. With point 3 of the previous sub-paragraph a clear dilemma is raised. To improve the current procurement processes, the board most likely introduces a solution that consumes more resources than the current processes. But to increase the likeliness that an improvement becomes accepted by the executive core, it should not consume any resources at all, as these are taken away from the core processes. Next to this dilemma, it is at this time unclear what actually is done during procurements, named in point 1. For this research it means that first it has to be analyzed what is currently done in procurements so to come to a choice of a device. Only then it becomes possible to advise an improvement for the procurements.

Summarized, it is currently not known what should be improved about procurements. It is known that something should be improved, as that is required by law and because it is wise to do in order to stay competitive with other hospitals on quality. The problem that the problem owner faces is summarized in the problem definition shown below.

The executive board of the hospital wants to improve procurements, as at this moment procurements of medical devices are not compliant with the law and not effective in creating a safe environment during use. The advice to improve procurements must be acceptable for the executive core, as they are crucial for the successful use of the improvements.

- problem definition -

As stated in point 1 of the previous paragraph, it first needs to be researched how the current procurements are carried out, as there exists only one researched case. This also needs a more specified answer to what actually is ‘acceptable’ for the executive core.

In this research it is assumed that the procurement of a medical device is the first process controlled by the hospital itself in the whole life cycle of a medical device; from idea, to product until the end of its life. The LUMC is most probably involved in research and development of some medical devices. Assuming that the procurement of a medical device is the first process controlled by the hospital itself is a scenario that is valid for most of the devices in the LUMC.

§ 1.4 The life cycle of medical devices within the hospital

This research requires a clear definition of what a procurement is and what its relation is with the other steps in the life cycle of a medical devices within the hospital. Only then is it known what is under study and what the relation is with the other parts of the life cycle.

The following description is conceptual but plausible. The primary purpose is to have a reference that can be used to structure the data gathering and analysis that is done in this research. This description describes a medical device life cycle from the viewpoint of the hospital. The description does not start
with the idea of a new technology (that is a producer view), but with the idea that a new device is required. The phases of the life cycle:

Device wish

A life cycle in the LUMC of a medical device will always start with a wish for a device. For example, a doctor hears of a device that makes a certain treatment possible or better, or the stock of a good that is not reusable (meaning disposable) is almost depleted.

Budgeting

A wish for a device must be supported by a budget. A system that distributes budgets is present in every hospital. The system will test certain requirements and then grant or decline the budget request. When a budget is granted to a certain wish for a medical device, the procurement of that device will be started.

Procurement

For most types of medical devices there are a variety of producers on the market. Most probably there also are companies present who are specialized in distributing medical devices to medical centres, the suppliers. Furthermore it is important to think about compatibility with the medical devices and other systems (air supply, electricity, ICT) that are already in use. As described in § 1.3.2, there are problems with procuring safe medical devices. When a device is purchased and accepted by the hospital, the procurement phase is finished.

Introduction

After the device is accepted by the LUMC by the release procedure, it needs to be introduced into the hospital. Depending on the device, this could imply storing the device for later use (disposables) or assembling the medical device (MRI, CT). It is possible that time consuming activities, such as a construction of a suitable room, should be started already during the procurement. Some medical devices can be complicated to use, which requires proper education and training of all personnel that will use the device. This at least has to be done once during the introduction, but one can think of situations in which it is important to repeatedly train and educate the users. In this report the education, training and perhaps other work that is necessary before a device is taken in use, is called ‘introduction’. The introduction ends when the device is in use for regular patient care. The transition between introduction and use can be vague, as it can be that the device is already in use while not all users are trained.

Use

When the introduction is finished, a medical device can be used for medical treatments. Use is the longest phase of the life cycle, as it concerns the use of specific. Some devices will be preventively checked and repaired, some will not. Preventive maintenance is a very important precondition to increase patient safety (WIBAZ, 2005).

During use, all kinds adverse events can happen with the new device. Already during a procurement it could be possible to think of actions to prevent these events from happening, or mitigating the effects of these events.
End-of Life

For all devices there is a time that the device can no longer by used. For a disposable device this is clear; after it is used. For a device that breaks down and cannot be repaired it is also a clear case. But what if the device has broken down, but can be repaired for costs equal to half the price of a new one? Or when a device still functions well, although financially it has reached its end? Or if a new devices promises to be significantly more efficient? The end of a product in the hospital is not as trivial as it seems. How hard it is to determine depends on many factors, related to the device itself, the environment it is used in and to technological evolutions and revolutions.

Life cycle figure

This life cycle in the hospital is summarized in figure 1.3. It shows the introduction of two specific device types, of which one replaces the other. There are situations in which a device type is not replaced with a new one if it has become obsolete, which ends the life cycle. By using two spirals, two views are represented; that of the specific device type that is ended after several years of use, and that of the general device type that offers certain functions to the hospital. With a specific device type, a specific type of a specific producer is meant. With general device type a certain group of devices that provides a function to the hospital is meant, for example a breathing apparatus. Three last notes about the figure; first, the colours are used to communicate a difference between phases. Second, the length of the phases is only indicative. Third, the positions of the phases of the first and second medical device in relation to another are just indicative.
§ 1.5 Research boundaries

In § 1.3 the problem is defined for the problem owner. In this research only a partial solution to the problem will be given, as the total problem is too broad and various to be dealt with in a graduation project.

There are several research boundaries discussed here. Together these boundaries make clear what is researched and what is not. But because first it is important to know how currently procurements are carried out before an advice can be given, these boundaries still provide a broad research area. At this moment it is not known what should be improved, so the research boundaries for the advice can only be given when it is known what should be improved. These research boundaries are given later on in the research, in Chapter 6.

Advise on what should be introduced, not how

If the board starts implementing a solution for the problem, it is important to clearly communicate the need and benefits of the new solution to the hospital staff in general and to the experts specifically. The diplomacy to introduce this will not be part of this research, but in the end of this research it does have to
be clear what the benefits are for the hospital as a whole and for the experts specifically. The emphasis of this research remains the advice of what should be introduced.

**Only medical devices**

One unclear part is the definition of a medical device (*medisch apparaat*) used by personnel compared to the definition of a medical appliance (*medisch hulpmiddel*) used in the Dutch law. A medical device is not a term used in the laws, while medical appliance is. The term medical device includes many more devices than what is probably meant by the LUMC with medical device. It is important to work with a clear definition in this research. This research will only provide a solution for the procurement of medical devices, not for other procurements.

**Purchases and gifts**

The definition of a purchase is clear; it means that a certain amount of value is exchanged for a good or service, but in academic hospitals not all medical devices are actually bought. Producers sometimes provide devices for free to the hospital, so they can promote the use of their devices by an academic hospital, or to profit from the use of disposable parts. This is not a purchase as in the definition. But it does introduce devices into the hospital and thus creates a potential source of an adverse event. The devices that are provided for free are part of this research.

**Only CE certified medical devices**

An academic hospital is active in research, also for and with new medical devices that are not yet CE certified under European law. By law, non-certified devices can only be given to a hospital by producers and require a judgement on safety and ethical aspects from a hospital commission when it is used on patients. The non-CE certified devices would not be dealt with in this research, as those devices are not part of regular patient care and are already judged. More on the CE certification can be found in § E.2.

**Only advice about procurements**

When the description of § 1.4, is used to define a procurement, it is everything between the end of the budget decision and the beginning of the introduction. The transition criteria turn that into a useful definition. These definition criteria are given above and are shown outside the lifecycle spiral in figure 1.3. A procurement begins when a budget decision is taken and ends when the device is accepted and paid by the hospital.

This research will only advise the way procurements could be improved. Nevertheless the budget decision is described in this research, so to clarify what is input for the procurement. It is possible that is influencing how procurements are carried out at this moment.

**Summary of the research boundaries**

All the previous definitions are summed up into the following 4 research boundaries.


1. This research will provide a solution how the process can be improved, not how the process should be introduced.
2. This research will focus only on medical devices
3. Purchases and gifts of medical devices are part of this research
4. Non CE certified devices are not part of this research.
5. The focus of this research is on the procurement and resulting outcome, not budgeting, use or end-of-life processes and decisions.

- research boundaries -

§ 1.6 Research questions

This paragraph states the research questions. First the structure of raising research questions is explained. After that is clear, the main research question and relevant sub-questions are stated.

§ 1.6.1 Structure of raising research questions

As explained in the paragraph that defined the problem (§ 1.3), there is not enough knowledge about the current way procurements are carried out. The sub-questions that are stated below (§ 1.6.3) will research in dept what areas require an advice. This will most probably provide several areas within the procurement process that require an advice. This requires a choice amongst these areas, which will be based on urgency. Chapter 6 will deal with the sub-questions that are required to form an advice. Here the sub-questions that are required to investigate the procurement are explained.

§ 1.6.2 Main research question

The main research question is based on the problem definition and the research boundaries. It is the leading question throughout this report and will be answered in the end of this report.

How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?

- main research question -

The problem definition stated in § 1.3 is true for both the executive core and for the hospital board. Both are responsible for the safety of patients and personnel, both face the same problem. But their goals within the hospital and the means available are somewhat different. The problem owner, the executive board, is dependent on the executive core for their knowledge and benevolence to change their working processes. At the same time the executive core is dependent on the executive board for resources and support to make their processes possible.

§ 1.6.3 The sub-questions

In this sub-paragraph each sub-question is explained one by one.
Sub-question 1: What is the definition of a medical device?
In the problem definition the term medical device is used. But at this moment it is not known what is meant with this term. This sub-question ask the question what it means, so to have it clear what this research is actually about.

Sub-question 2: What is seen as a qualitative good procurement?
Procurements can be done in many different ways. But in essence they all provide one outcome; a decision basis of what to be procured. This sub-question raises the question what can be seen as a qualitative good procurement. Only with this answer is it possible to improve procurements. This sub-question provides an input for sub-question 4.

Sub-question 3: In what way are procurements currently carried out?
To improve procurements, it first needs to be known how currently procurements are carried out. At this moment only one example is present, so more examples are presented, as well as a general idea of how procurements are carried out. This question will provide an input to sub-question 4.

Sub-question 4: What should be improved in the current way procurements are carried out?
This sub-question investigates what should be improved, by comparing sub-question 4 with sub-question 3. This will likely provide several areas that require improvement. This leaves open the question which area will be subject of advice in this research. That is answered by this sub-question.

§ 1.6.4 Summary of the sub-questions
Here a summary is given of the sub-questions that seek the current areas that require improvement, which will be referred to throughout the report. The sub-questions for the advice are given in Chapter 6.

1. What is the definition of a medical device?
2. What is seen as a qualitative good procurement?
3. In what way are procurements currently carried out?
4. What should be improved in the current way procurements are carried out?

- research sub-questions -

§ 1.7 Research approach
This paragraph explains how the research is carried out, the research approach. This is answered per sub-question.

§ 1.7.1 Approach to answer sub-question 1
This sub-question is a definition question, in this case desk research is appropriate. This can be answered by investigating what is already answered in the literature and laws. From the literature of the professional organisation there was not a workable definition found of what can be seen as a medical device. Sub-question 1 is therefore answered by seeking an answer in the law. The law provides a lengthy and detailed description on what can be seen as a medical device.
§ 1.7.2 Approach to answer sub-question 2

Procurement quality can be defined in two ways. First, the organisation itself could define what is seen as a good procurement. For sub-question 3 interviews were taken in the LUMC, so it might just as easily be asked what is seen as a good procurement and then form it into a definition. However, most likely this will result in a variety of definitions of what is good, seen from the perspectives of each individual actor. Furthermore these interviewed actors can be biased in their answer. They are directly connected to the consequences of what is seen as good, as they have to be part of possible improvements.

A different approach to define what is a good procurement has to be found as asking the staff to define what could be seen as a good procurement will most likely lead to a definition that is influenced by stakes of the interviewees. Therefore it is searched to come with a definition of an independent expert in the field of healthcare. This is found in the accreditation organisation of hospitals. The requirements the accreditation organisation sets for procurements are seen as indicators of what can be seen as a good procurement.

§ 1.7.3 Approach to answer sub-question 3

A procurement is a decision process in which it is decided what is purchased. Any decision process consists of intangible and tangible interactions and results. For example meetings in a procurement group will have many interaction and will then be documented somehow, the contract will be a discussion in word and on paper between the hospital and the supplier with a resulting contract. This tangible part of the procurement is most often a summary of preceding discussions, meetings or any other type of human interaction. These interactions take place because (a part) of the project group sees is as valuable to the process, and / or because it is prescribed by the regulation of the LUMC or by relevant laws (think of regulation for tenders). In order to study the current process, it is therefore possible to study the regulations, or the actors that take place in procurements, or both. In this research it is chosen to study the procurement by means of interviews. There is one important reason for this choice. That regulation is present does not mean that it is actually in use by the staff that performs procurements. Studying the processes will then tell very little on what is actually done. An interview rules out that a protocol is studied that is not in use.

Interviews provide qualitative information. Actor interviews have the advantage of presenting what is really done by these actors to come to a good procurement decision. In order to discover as much qualitative data in the interviews as possible, a semi-structured interview scheme was preferred above a tight questionnaire. This better fits interviewing staff of all different kinds of occupation from within the LUMC, and it provides room for adaptations into directions of interest. As the interviews were done for the whole life cycle of medical devices within the hospital, a part of all interviews was also reserved for budgeting, introduction and maintenance routines. For this research project, the following areas were questioned:
- Function(s), position in organisation, role and responsibilities related to that function
- Procurement involvement, role and responsibility of others and themselves
- Examples of procurements the interviewee was involved in
- What is going well and what is not going well, related to the procurement
- The possible improvements that should be implemented
The interviews were all held face-to-face, were taken during working hours, and the location was a private room within the LUMC.

The executive core, the medical staff, starts all procurements for medical devices. That is why the executive core is represented in the selection of interviewees. They are the ones that have knowledge and experience about the user side. During procurements the facilitating departments are involved as well, as they have knowledge about the other aspects of a device.

The interviewees are selected from throughout the LUMC, from all ranks of the divisions, an executive board member and from all related facilitating services.

§ 1.7.4 Approach to answer sub-question 4

The answers found in sub-questions 2 and 3 are used to make a comparison of what is seen as a good procurement and if that is actually currently in use by the LUMC. This will provide an answer of what is currently open for improvements.

As this is a very broad question, several areas that are open for improvements can be found. This requires a choice amongst these areas to focus on. The basis of this choice is developed in the chapter that provides the answer to sub-question 4.

§ 1.7.5 Approach to answer other sub-questions

The approach to solve the other sub-questions will be described in more detail whenever it is clear what should be improved. In general it will be tried to form an advice based on available literature and analysis and ideas to solve the problem.

§ 1.8 This report

The report is divided in four parts; Definitions, data gathering and analysis, design of an advice, and
Part 1 is called ‘Definitions’. It contains chapter 1 and chapter 2. Chapter 1 defines this research. Chapter 2 defines ambiguous terms that are used in the problem definition, which answers research sub-question 1. And it answers sub-question 2, what is seen as a qualitative good procurement.

Part 2 is called ‘Data gathering and analysis’. It contains chapter 3 to 5. Chapter 3 presents the data of the budgeting phase, which forms the input for the procurement process. Chapter 4 presents the data of the procurement phase, which answers research sub-question 3. Chapter 5 compares the answers to research sub-question 2 and 3. This analysis provides the answer to research sub-question 4, what should be improved. With this information a selection is made for which area an advice is formed.

Part 3 is called ‘Design of an advice’. It contains chapter 6 to 9. Chapter 6 provides the approach and sub-questions that are required to form an advice, which answers the main research question. Chapter 7 presents the indicative factors of procurement quality. Chapter 8 identifies the possibilities that are present to improve the procurement quality. Then Chapter 9 provides the advice and the argumentation for the advice, which answers the main research question.

Part 4 is called ‘Conclusion’. It contains chapters 10 to 13. It provides the conclusion to the research questions in Chapter 10. Chapter 11 provides an advice to the executive board of the LUMC. Chapter 12 names the research gaps that remain and are discovered during this research that are interesting to study in a follow up research. Chapter 13 reflects back to the research and reviews the processes of this research project.

After part 4, the resource list and the appendices are given.
CHAPTER 2. REGULATION, NORMS AND INITIATIVES

Chapter 2 will present all the relevant laws, norms and initiatives from professional organisations and the authorities. In § 2.1 the answer is given to:

Sub-question 1: What is the definition of a medical device?

In § 2.2 the answer is given to:

Sub-question 2: What is seen as a qualitative good procurement?

§ 2.1 Definition of ‘medical device’

Within the hospital the definition ‘medical device’ is used. It is presumed based on the actor interviews that it refers to anything electrical or mechanical that is connected to a patient and is needed for care (medical). In the laws, no such term as medical device is used, but the term ‘medical appliance’. This suggests that it includes many more things than the term ‘medical device’ does.

In order to leave behind the suggestions and come to a clear definition on what it means when the term medical device is used, this paragraph will explore the definitions that are used in the Dutch regulation. Using definitions from the regulation has an advantage above making ones own definition; the laws are valid for the definition coming from the law. This makes it possible to include a description of what influence the laws have (or do not have) on the procurement of a medical device.

The argumentation of what is included, what is not included and why is to be found in Appendix D, and is summarized beneath table 2.1. In general, the definition of a medical device used in this report (table 2.1) will be the same of the definition for a medical appliance from the Law medical appliances.

<table>
<thead>
<tr>
<th>table 2.1</th>
<th>definition of medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any instrument, apparatus or device, any substance or other article, alone or in combination, including the required software for its proper functioning, and that it is intended by the producer to be used with humans for the following purposes:</td>
<td></td>
</tr>
<tr>
<td>- Diagnosis, prevention, monitoring, treatment or alleviation of disease,</td>
<td></td>
</tr>
<tr>
<td>- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,</td>
<td></td>
</tr>
<tr>
<td>- Investigation, replacement or modification of the anatomy or a physiological process,</td>
<td></td>
</tr>
<tr>
<td>- Control of conception,</td>
<td></td>
</tr>
<tr>
<td>For which principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but such appliances can support this.</td>
<td></td>
</tr>
</tbody>
</table>

Excluded from the definition of a medical device are (stemming from § D.1):
- Custom sized medical appliances and medical appliances meant for clinical research
- Devices containing human blood, tissue or cells and transplants or any derivative from human origin when being sold, except derivatives from human blood
- Human blood, tissue or cells and transplants from human origin or any derivative from it
- Devices containing animal blood, tissue or cells and transplants from human or animal origin when being sold, unless the origin is from a non-viable animal origin
- Medical appliances that are indivisible of the medicine it administers, or are disposed after administering the medicine.
- Personal protection appliances

The definition of what a medical device is, includes (stemming from § D.1):
- Active medical appliances, also for therapeutic or diagnostic purpose
- Reusable surgical medical appliances
- Invasive medical appliances, with or without a surgical nature
- Implantable medical appliances, including active implants
- In-vitro diagnostics
- Aiding appliances (including software) needed for the proper function of the medical device

§ 2.2 Definition of a good procurement

Leading within the LUMC is the NIAZ (Dutch Institute for Accreditation in Healthcare; Nederlands Instituut voor Accreditatie in de Zorg) quality norm. The NIAZ is a accredit organisation, which is also by the authorities seen as leading. In this paragraph, the descriptions the NIAZ uses to judge procurements are explained. The NIAZ refers to other Dutch organisations as well, for more details or as external norms. These descriptions of IGZ, WIBAZ, OMS and NVKF are also discussed here.

The norms that are presented here are to be seen as snapshot. In a couple of years the norms will probably be changed by progression of knowledge in the health care sector.

§ 2.2.1 NIAZ quality criteria for procurements

The NIAZ (Dutch Institute for Accreditation in Healthcare) was established by PACE (predecessor of NIAZ), OMS, NVZ and VAZ at the end of 1998. From 2003 on, the board of NIAZ consists out of representatives of healthcare organisations, professionals, healthcare insurers and consumers.

NIAZ strives to contribute to a guaranteed and ever improving quality of the healthcare sector, by developing quality norms and by applying these norms in accreditations of healthcare institutes and processes. This should provide a possibility for consumers, insurers, government, investors and society to judge healthcare providers on the reproducibility, safety and adequacy of the delivered care. These norms provide healthcare providers an opportunity to improve their quality of care in a structured and widely accepted manner (NIAZ, 2008).

NIAZ accredits healthcare organisations on basis of what is present, and not so much on how that is achieved. This is in line with the philosophy of the Quality Law for healthcare providers. The terms ‘regulation’ and ‘quality’ are often used in this context. NIAZ has defined this as:
Part 1  Definitions

| Regulation | The whole of agreements and provisions of staff and goods, which are arranged to reach an agreed and planned result. ‘Agreements’ can be regulations, procedures, protocols, (work) instructions, and other notes. It also includes all organizational policies, like responsibility and authority distributions and the appointment of officials. ‘Staff provisions’ can be the attraction of experienced employees and the maintenance of their knowledge level. ‘Material provision’ includes all physical facilities, like accommodation, devices, IT, appliances and materials. The robustness of the regulation is determined with help of the scoring system that is part of the assessment system. |
| Quality | Quality is the measure in which: The intended results that are relevant for the patient are achieved in time and with dignity for the patient (≡ narrow definition of quality) Without unintended and harmful events for patient, employee and visitor (≡ safety) This definition thus always includes safety, unless stated differently. |

The system that NIAZ uses to accredit is called the INK model (Dutch term), or EFQM (European term). NIAZ uses the INK model for practical reasons; most hospitals already use some form of it, and it was suitable for ordering the quality criteria in a logical manner together with the relevant links between the quality criteria.

The INK-model is a model that arranges the operational management in a logical manner and provides links between the management disciplines. NIAZ filled in this model with different quality criteria in the report that states and explains all the quality demands, called ‘Kwaliteitsnorm Zorginstellingen 2.1’ (Quality norm Healthcare Providers 2.1). figure 2.1 presents the model from that NIAZ report. The operational discipline in which procurements are defined is block 4, Management van middelen, or Management of resources.

In the quality norms of block 4, the NIAZ has a category called Purchase and Outsourcing (Aankoop en Uitbesteding). In that category one group of norms is relevant for procurements (# 411.xx, table 2.3.). The other group of norms is relevant for outsourcing (# 412.xx).

@TUDELFT
### table 2.3 relevant norms of the NIAZ, category purchase and outsourcing (NIAZ, 2009)

<table>
<thead>
<tr>
<th>Norm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>411.01</td>
<td>The institute has a regulation for the procurement of all the kinds of goods that are used within the institute. This regulation specifies the following points:</td>
</tr>
<tr>
<td>411.01a</td>
<td>The way that experienced employees are involved in the selection process, if the procurement is for goods or devices used in the healthcare processes</td>
</tr>
<tr>
<td>411.01b</td>
<td>The way in which the selection and judgement of the suppliers of goods is carried out</td>
</tr>
<tr>
<td>411.01c</td>
<td>The way in which the investments in medical devices and other goods fit within the (strategic) policy and the derived budget of the institute</td>
</tr>
<tr>
<td>411.02</td>
<td>The institute has a regulation for tracing and retrieving material, goods and devices when the producer and/or the authorized external agency signals a shortcoming that is judged as unsafe (recall procedure) [part of NTA 8009:2007]</td>
</tr>
</tbody>
</table>

Norm 411.02 is arguable to be specifically part of the procurement. It is a norm that is applicable in procurements as then the product needs to be labelled, but it is of more importance during use, maintenance routines and when taking out of service. So it has more to do with the management of devices. Therefore, only norm 411.01 is used in this research.

Next to the category for procurements, there is another category in block 4 (figure 2.1) that has relevant norms for procurements. The category is Devices, Information technology and Infrastructure (Apparatuur, Informatietechnologie en Infrastructuur). The relevant norms come from the groups Devices (421.xx), Information technology (422.xx) and Infrastructure (423.xx) and are listed in table 2.4.

### table 2.4 relevant norms of the NIAZ, category device, information technology and infrastructure (NIAZ, 2009 - p44 - )

<table>
<thead>
<tr>
<th>Norm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>421.01</td>
<td>The institute has regulation for the process of risk analysis in the beginning of a procurement of (medical) devices, meant to guarantee the quality during use. [part of NTA 8009:2007]</td>
</tr>
<tr>
<td>421.03</td>
<td>The institute has regulation for the experimental placement and start of use of new (medical) devices, with one of its aims being a responsible release for use. This includes: [part of NTA 8009:2007]</td>
</tr>
<tr>
<td>421.03a</td>
<td>The technical responsible person and the real users are involved</td>
</tr>
<tr>
<td>421.03b</td>
<td>A manual / instruction for, and training of, employees who will operate the device</td>
</tr>
<tr>
<td>421.01c</td>
<td>A manual / instruction for, and training of, employees that are involved in the maintenance en repairs of the device</td>
</tr>
<tr>
<td>422.01</td>
<td>The institute has regulation for the availability and safety concerning information that meets requirements for data and information services regarding: privacy (protection against unauthorized acquaintance), integrity (security against lose or uncontrolled changes and additions) and availability (users can access it any moment). This regulation gives attention to the following issues: [only relevant sub-norm is named here] [part of NTA 8009:2007]</td>
</tr>
<tr>
<td>422.01h</td>
<td>Procurement, development and maintenance of information systems</td>
</tr>
<tr>
<td>423.05</td>
<td>On regular intervals and before a construction work, renovation and replacement of installations will the safety risks be analyzed and if necessary reduced by timely preventive actions. [part of NTA 8009:2007]</td>
</tr>
</tbody>
</table>

Without question is it clear that norms 421.01 and 421.03 are relevant for procurements of medical devices. The NIAZ refers to standards that are developed by Dutch institutions, namely from the IGZ, NVKF, OMS, and WIBAZ, which will be discussed in the coming sub-paragraphs.
Norm 422.01 is relevant for information technology. This norm is relevant for the procurement of medical devices that use ICT as described in the definition of a medical device table 2.1.

Norm 423.05 is relevant for the infrastructure of the building. It is partly relevant for this research. An infrastructural change can be required before a new device can be used. For example, an MRI scanner requires a cage of Faraday to be operated in. Within the procurement NIAZ requires there to be a risk analysis. That is the relevant part of this norm for this research project. The part that describes that risk analyses should be done for all infrastructural changes and on regular intervals, is not relevant for this research project.

This paragraph described the requirements that should be present in a procurement. NIAZ defined ‘present’ as ‘operational in use’, not only ‘available on paper’. The NIAZ norms are the most detailed norms for procurements present, and is also seen by the IGZ as a proof of the compliance with the Quality law for healthcare providers.

In Chapter 5 the actor interviews will provide insight if these NIAZ requirements are actually present. One note here is that the LUMC just received a NIAZ accreditation this year (June 2009) and is the first hospital that has been accredited three times. So theoretically everything should be present.

§ 2.2.2 IGZ requirements for procurements

The two reports the NIAZ refers to from the IGZ, are Kwaliteitsborging van medische apparatuur in ziekenhuizen: verbetering noodzakelijk (Quality improvement of medical devices in hospitals: improvements necessary, 2002) and the follow up report Kwaliteitsborging van medische apparatuur in ziekenhuizen: nog steeds onderschat (Quality guarantee of medical devices in hospitals: still underestimates, 2005). In § E.1 all reports of the IGZ that are relevant for this report are summarized. A small summary of the relevant parts of the two reports referred to by the NIAZ is given here.

The 2002 report of the IGZ was based on a questionnaire amongst 103 Dutch hospitals. It gave a general view on how the situation was in the Dutch hospital system, and the recommendations to improve safety regarding the use of medical devices in hospitals. The recommendations state what the IGZ sees as a good procurement. The eight recommendations the IGZ names are summed up in § E.1. The first five recommendations and the last recommendation named in that paragraph are relevant for procurements (indirectly or directly) and are translated here into requirements for procurements (IGZ, 2002a):

1. A managed and guaranteed quality management system should be present; it should be described, defined, operational and monitored (general requirement, valid for procurement)
2. Risk management should be carried out and should lead to risk control measures (general requirement, valid for procurement)
3. Responsibilities should be defined and clear for the whole organisation (general requirement, valid for procurement)
4. Acceptation procedures should be present (specific demand for procurement)
5. The introduction processes of new devices on departments should be a guaranteed and obligated process (specific demand for procurement)

Source: http://www.lumc.nl/0000/13043/13073/906031146585721 (retrieved 01-08-2009)
6. Storage locations must be present for all devices, and this can be anticipated within procurements (specific demand for procurement)

Point 1 here is what is tested by the NIAZ norms. Point 2 is directly related to norm 421.01. Point 3 is directly related to norm 421.01 in general and 411.01 specific. Point 4 is directly related to 411.01 and its sub-norms a, b and c. Point 5 is directly related to 421.03 and its sub-norms a, b and c. Point 6 is not clearly defined, but could be seen as part of norm 423.05.

All taken together, only point 6 could add to the NIAZ norms. This is no coincidence, as the NIAZ norms more recently published and are also based on IGZ norms.

The 2005 report of the IGZ to which the NIAZ refers to is based on a follow-up research of the report of 2002. It recognized improvements, but also detected new shortcomings. In § E.1 the recognized problem are summarized from the report. The recognized problems are here again translated into requirements for procurements. The requirements for procurements are:

1. A procedure must be present for the introduction of new devices. A hospital must be capable of guaranteeing that staff is competent and authorized to operate a new device.
2. Acceptation test should include technical and user requirements
3. User instructions should be available in a Dutch manual

Point 1 is related to norms 421.03b and 421.01c, specific and indirectly with norm 423.01. Point 2 is directly related norm 421.03a. Point 3 is an addition to norm 421.03b.

Again it is clear that the NIAZ has included the IGZ requirements in their norms. Only point 3 is an addition to norm 421.03b.

§ 2.2.3 WIBAZ risk framework

The NIAZ refers to a report of WIBAZ (Werkgroep Instrumentatie Beheer Academische Ziekenhuizen, or Working group Instrumentation management of academic hospitals), together with NVZ, VZI and NVKF, which provides theoretical background and some checklists. The WIBAZ report is named Een Risico Management Raamwerk Voor Klinisch Gebruikte Apparatuur (a risk management framework for clinical devices) and was published in 2005. As the title suggests, it provides a risk management framework for medical devices. A nuance here (and stated in the report) is that the report lacks practical guidelines. The largest part of the report builds a risk assessment classification scheme, based upon CE risk classes and by WIBAZ itself developed criteria. The criteria are not exhaustive.

WIBAZ, as instrumentation management group, spent a lot of attention to cause and effect between the factors ‘risk class’ of a device and ‘maintenance frequency’. The factors influence another in reality, as the risk class should increase if the maintenance frequency is low. But that does not provide a workable model. Therefore the WIBAZ has chosen to let the risk class be the cause that determines the maintenance frequency.

For procurements the WIBAZ has provided a list of factors that are causes and effects. The list is as follows; Investment need, market exploration, program of requirements, test placement, selection process, contract agreements, introduction, maintenance needs, and inventory administration. The list contains causes and effects. A more detailed list is announced in the report, but is not yet available.

§ 2.2.4 OMS guideline for the medical specialist

The OMS (Orde van Medisch Specialisten, Order of Medical Specialists) has given a guideline that makes the border clear between responsibilities for maintenance (OMS, 2008). The guideline provides
practical borders that are focused on the use of the medical device, not the procurement. For this research the guideline has therefore no practical relevance.

§ 2.2.5 NVKF performance indicators

The NVKF (Nederlandse vereniging voor Klinische Fysica, Dutch association for clinical physics) has translated the IGZ report of 2002 and the NVZ report of 2004 on general quality and security requirements into practical indicators for the processes of purchase, introduction and application of medical technology. These performance indicators provide a hospital insight into the quality control and guarantee and into effectiveness and efficiency of the medical device management. The NVKF wanted to avoid unnecessary bureaucracy and has therefore developed a limited amount of seven indicators. These seven indicators provide information on nine processes around medical devices. The table of indicators related to processes is presented in table 2.5.

<table>
<thead>
<tr>
<th>Process</th>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Risk analysis</td>
<td>a</td>
<td>Percentage of the total number of devices / systems in the database that is classified in risk classes based on an applied risk analysis</td>
</tr>
<tr>
<td>2 User protocols and instruction</td>
<td>b</td>
<td>Percentage of the devices taken in use last year and meant for clinical procedures that formally is released for use, only after the proper and safe functioning is determined and after having determined that the users are instructed using designated user protocols</td>
</tr>
<tr>
<td>3 Release for use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Effective management</td>
<td>c</td>
<td>Percentage per risk class of the total number of devices / systems in the database for which there is no arrear preventive maintenance</td>
</tr>
<tr>
<td>5 Periodic evaluation</td>
<td>d</td>
<td>Percentage per risk class of the total number of devices / systems in the database for which in the last year the technical status and functionality related to the technical process is assessed.</td>
</tr>
<tr>
<td>6 Investment budget</td>
<td>e</td>
<td>Percentage of the medical devices taken in use last year that is purchased and introduced based on an in advance determined investment budget and conform a predetermined procurement and introduction process.</td>
</tr>
<tr>
<td>7 Procurement and introduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Efficient management</td>
<td>f</td>
<td>Balance between the annual maintenance costs of the present medical devices and the total replacement value</td>
</tr>
<tr>
<td>9 Relation management</td>
<td>g</td>
<td>Is an evaluation system used for the assessment of the cooperation between Clinical Physics / Medical Technology and all the other responsible parties in the institute.</td>
</tr>
</tbody>
</table>

Reader note: Indicators a to e should ideally be 100 %, indicator f gives a balance and indicator g should be ‘yes’ including proof why it is yes

Indicator e can be used as a direct indicator for procurements. It demands for an investment budget, procurements description and an introduction process description. Connected to that is indicator a. This indicator demands for a risk analysis system in the hospital. It would be logical to assess the risks of a medical device somewhere in the procurement, be it just after budgeting, during specification of requirements, just before or after acceptation tests or just before releasing it to be used in the hospital, or an iterative risk assessment throughout the whole procurements. Connecting the risks of a device with the procurement gives a possibility to better judge risks for patients during the procurement. Indicator a and e will therefore be used as a requirements for the procurement.
§ 2.3 Answers to sub-questions 1 and 2
This paragraph provides the answers to research sub-questions 1 and 2 one by one.

§ 2.3.1 Answer to research sub-question 2: What is the definition of a medical device?
This is answered in § 2.1 by use of the relevant Dutch regulation. A medical device is:

Any instrument, apparatus or device, any substance or other article, alone or in combination, including the required software for its proper functioning, and that it is intended by the producer to be used with humans for the following purposes:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,
- Investigation, replacement or modification of the anatomy or a physiological process,
- Control of conception,

For which principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but such appliances can support this.

Excludes are the following of what could be seen as part of ‘medical device’:
- Custom sized medical appliances and medical appliances meant for clinical research
- Devices containing human blood, tissue or cells and transplants or any derivative from human origin when being sold, except derivatives from human blood
- Human blood, tissue or cells and transplants from human origin or any derivative from it
- Devices containing animal blood, tissue or cells and transplants from human or animal origin when being sold, unless the origin is from a non-viable animal origin
- Medical appliances that are indivisible of the medicine it administers, or are disposable after administering the medicine.
- Personal protection appliance
§ 2.3.2 Answer to research sub-question 2: *What is seen as a qualitative good procurement?*

This is answered in § 2.2 by use of the accreditation regulation of the Netherlands and references. The most important NIAZ quality norms are presented in table 2.6. This table is supported by the performance indicators of the NVKF, which are given in table 2.1. The tables combined provide the answer to sub-question 2. For the argumentation, please read § 2.2.

<table>
<thead>
<tr>
<th>Table 2.6</th>
<th>most relevant NIAZ quality norms</th>
</tr>
</thead>
<tbody>
<tr>
<td>411.01</td>
<td>The institute has a regulation for the procurement of all the kinds of goods that are used within the institute. This regulation specifies the following points:</td>
</tr>
<tr>
<td>411.01a</td>
<td>The way that experienced employees are involved in the selection process, if the procurement is for goods or devices used in the healthcare processes</td>
</tr>
<tr>
<td>411.01b</td>
<td>The way in which the selection and judgement of the suppliers of goods is carried out</td>
</tr>
<tr>
<td>421.01</td>
<td>The institute has regulation for the process of risk analysis in the beginning of a procurement of (medical) devices, meant to guarantee the quality during use. [part of NTA 8009:2007]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2.7</th>
<th>relevant NVKF performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>Indicator</td>
</tr>
<tr>
<td>1 Risk analysis</td>
<td>a Percentage of the total number of devices / systems in the database that is classified in risk classes based on an applied risk analysis</td>
</tr>
<tr>
<td>6 Investment budget</td>
<td>e Percentage of the medical devices taken in use last year that is purchased and introduced based on an in advance determined investment budget and conform a predetermined procurement and introduction process.</td>
</tr>
<tr>
<td>7 Procurement and introduction</td>
<td></td>
</tr>
</tbody>
</table>
PART 2. DATA GATHERING AND ANALYSIS
CHAPTER 3. THE BUDGETING PROCESS

Budgeting is taken into the analysis as it provides the input for the procurement process. It is found that this is of great importance for the procurement, as it leads to very different procurements.

This chapter starts with the presentation of the data of the budgeting process. The data presentation consists of a part that explains crucial definitions of the budgeting process (§ 3.1). After that the chronological description of the budgeting process is given (§ 3.2). After the presentation of the data, the analysis of this data is performed (§ 3.3). It aims at explaining the consequences of the current budgeting system on the procurement. It ends with a short summary (§ 3.4).

§ 3.1 Definitions used in the budget process

For the presentation data of the budget process, first two terms are explained to help the reader to understand the description of the budget process. The first term is investment type (§ 3.1.1) and the second term is budget form (§ 3.1.2). Then the budget process is presented in § 3.2.

§ 3.1.1 Investments types

Before a procurement starts, it has to be granted with a budget. There are different categories of budgets. The table 3.1 presents the different categories, which are based on the financial value.

<table>
<thead>
<tr>
<th>Type</th>
<th>Minimum (€k)</th>
<th>Maximum (€k)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>A</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>X</td>
<td>&gt;0</td>
<td>10</td>
</tr>
</tbody>
</table>

All actors agreed with the definition of C and B investments. All but two actors defined the minimum for an A category as € 0k. Two actors defined the A investment with a minimum of € 10k. Below € 10k, is a not an existing category. The purchase department does not have to sign for it, and neither does the department have to file it in to the division board. That is why it is called category X here.

§ 3.1.2 Budget form

The budget form is named throughout the interviews of the heads of facilitating services and with the division heads. It is used since the budgeting process for 2009, which took place in 2008. As it is a new form, it is improved this year to better support its function. It is introduced to improve the involvement of the staff departments, as they were sometimes not involved properly or on time. It is a form that has to be filled in for all B and C type investments by the budget requestor or project leader. The executive board bases their granting of budgets requests based on the budget form and other considerations.

In the form standard financial questions have to be estimated; the costs for the device, possible extra costs before the start (ICT, Infra, education, consults, others), operational costs (personnel, maintenance, other), how much years it will be operated, in how much years it is introduced (LUMC, 2009a). The form also asks if there was a meeting with the division clinical physicist to discuss safety and control measures if the investment is for a high-risk device. The risk classification by the LUMC of devices is explained in § 4.4.2.
Furthermore it asks if a similar device is in house, when it will become active, the location, contact details and a thorough motivation why it should be purchased.

Next to that, it asks for a motivated argument why a staff department should not be involved. If it is necessary to involve them, a summary of a meeting with that staff department has to be included together with risk and control measures. It questions the following for these staff departments:

- Purchase department; was there a meeting that discussed the procurement form and European tenders?
- Infra; was there a meeting about construction changes or additional utilities?
- ICT; is it needed to involve ICT?
- Instrumental services; was there a meeting about the whole life cycle of the device?
- VGM; was there a meeting about radiation, occupational health and safety affiliations?
- Sterility; was there a meeting about sterility issues?
- HRM / Boerhaave\(^\text{10}\) / Supplier; was there a meeting about education / training for use of device?

### § 3.2 The budget process data

Each year a budget process is started and ended to determine the budget distribution of the following year. The executive board of the LUMC manages the financial resources of the LUMC. It distributes and grants funds for requests. As this research is about medical devices, this wish for a budget will always come from a medical department.

As the total value of the requests is larger than the total amount of budget, in the budget process the requests are prioritized. Two types of processes are present in the LUMC to prioritize budget requests amongst the divisions and departments in the hospitals. The type of process depends on the size of the budget request. X and A investments are processed differently compared to B and C requests.

### § 3.2.1 X and Y budget requests

Each year each division is appointed with a lump sum budget for their A and X investments. The size of the lump sum is determined upon the total available budget of the budget, and a historically grown distribution amongst the divisions and departments. So there is not an actual request for a certain medical device. It is up to the departments themselves to use the budget wisely. The decision in what to invest is made by a department head, in consultation with its staff. This flexibility is needed to support the departments in providing care.

Division 1 does not ask the departments for a list of their X and A requests. Division 3 does request a list of all the A investments of the departments, in order to have some insight in the requests. The division board does not involve itself in these requests, as it wants the departments to use their freedom wisely.

The lump sum budgets for departments are seen as a kind of exploitation budget that is needed to maintain the provision of a medical procedures.

The lump sum for X and A investments are distributed to the departments each year. The budget cannot be saved up for the coming years. Typically, this leads to a run on purchases at the end of each year. This is a potential area of huge improvements in efficiency with the budget.

\(^{10}\) Educational institute of the LUMC
§ 3.2.2 B and C investments

For B and C investment requests, there is no lump sum. Each year the executive board prioritizes all the requests for B and C investments for the whole LUMC. This prioritization is done with three different criteria. The first criterion is the discussions with the division heads. The division heads already indicate a preference for investments to the executive board. The second criterion is the budget form (§ 3.1.1), which contains a motivation of the requestor and advises from all relevant facilitating departments. The third criterion is the compliance of the request with the strategic plan. All is limited by the available budget of course.

These three criteria are used to prioritize the all requests. The budget requests are then granted until the budget is finished. The executive board tries to distribute the requests fairly to all divisions, but does not provide a motivation for their choices to division heads.

There is a difference to how a division provides the budget request to the executive board. Most divisions will directly present all requests to the LUMC executive board, without providing the executive board with a priority in these requests. One division does provide a prioritized list of B and C investments to the executive board. For the prioritization of its own B and C requests that division has developed a prioritization approach. First the department heads make trade offs in the requests they have in their own departments. Second, an advisory commission consisting of the department heads is formed to judge each request. Last, the management team of the division selects the investments to present to the board based on the advice of the department heads and based on historical trends.

The whole budget process is shown in figure 3.1. It shows the processes that are carried out and the resulting outcome. Most of the outcome is input for another process.
§ 3.3 Issues with the budget process

Until now it is simple; a certain budget request will fall in a certain category, which will result in a different budget process, either a lump sum for a whole division (type X and A investments) or a selection by the executive board (type B and C investments). There are however five issues that complicate the budgeting process.

§ 3.3.1 Classification of a budget request: internal freedom to classify

The first two issues that are present with the budget form stem from internal classification freedom. As a result, a budget request can be treated in a lower category than expected.

1. The only reason why the syringe pump procurement, which costs several million euro, became known in the board, was that it had to be bought via a European tender (§ 4.5.1), something that has to pass the board. It is possible to spread a budget over several years, if it is an exploitation (replacement) of an obsolete device. If it was chosen to introduce the new syringe pumps in 10 years, the needed budget would be 10 times smaller and it would probably be an A investment.

2. The procurement team of syringe pumps decided to introduce the new pump everywhere at once. Then it was obligated by EU regulation to have a European tender (part of the procurement) while the budget (budget process) was not reviewed by the board as it were many type A investments from and for many different departments.

In short, it is possible to change the budget category of a request by alternating the number of years in which a medical device is introduced or by spreading the investment over multiple departments.

§ 3.3.2 Classification of a budget request: Suppliers offering discounts or gifts

Then there are yet two other issues that result in a wrong budget classification, which are not determined by internal decisions, but external decisions:

3. Then there is yet another possibility to place a medical device in another budget category, by getting a discount from the supplier. The LUMC as an academic hospital receives discounts from suppliers and producers, as they like to boost their image with an academic hospital using their equipment and because of business models that rely on profit by the continuous use of disposable part. If in an early market study to estimate the price a discount is offered, the device will be classified in a lower category. The discount could turn a medical device of category B in a category A after discount. If that happens, the budget is used from the lump sum, instead of being requested from the board.

4. As the LUMC is an academic hospital with the image of being the top of clinical care, it is apparently attractive for producers to not only give discounts, but to provide the device for free to the LUMC. This did created problems like missing budget for infrastructural changes that were required to operate the device or missing maintenance contracts.

An great difference between category X devices and given devices, is that category X devices represent their real value, while the given devices could even have the value of devices out of budget category C. But given devices with representative budget equal to category B or C are not part of the budgeting process. Moreover, this means they are not reviewed with the budgeting form (§ 3.1.2). And
these devices were not in a competition with similar devices. This creates a possibility of introductions of
devices that are not the best choice, if the price is left aside.
The interviewed actors did see the danger of the given devices. No one supervises their introduction as
would be done with regular items.

§ 3.3.3 Lump sums leave decision up to departments

The last issue that is found is a result of a trade of that is made internally in the LUMC. It is a trade-off
between control and flexibility.

5. The budget for X and A investments is distributed as lump sums, leading to a lack of oversight on
these investments, little insight in the (fair) distribution amongst the different divisions and to budget
runs on the end of the year. The lack of oversight is a potential threat for the safety of patients.

The distribution of the lump sum budgets over the divisions and then over the departments is a process
that leads to little insight in the effectiveness of the distribution. Not one interviewee recognized this to be
an issue for budgets. It does lead to a situation in which the departments themselves can quickly acquire
a device if it is suddenly needed. This is a first trade-off.

Another result is that the lump sums prevents a guaranteed system in which the requestor of the budget
has to discuss its investment with other parties, as is needed with B and C investments with a budget
form. But this does saves work to be done by the facilitating departments. This is a second trade-off.

The choice in the past is made to not control all the budget requests in detail. That does lead to a
situation in which budget requests can be added into a different category without any check if that is
correct (problem 1 to 4). And it leads to a situation in which efficiency is not stimulated, specifically for
investment types X and A (problem 5).

§ 3.4 Summary

Before the procurement of a medical device starts, one has to request a budget.

For investments between € 100k and € 500k (B type investments) and above € 500k (C type
investments) a budget is requested from the executive board of the LUMC. For type B and C investments,
a budget form has to be filed in, which give general indications about the requested budget and medical
device (). It asks questions about the life expectancy of a device, LUMC risk class and its facilitating
needs, like ICT, infrastructural changes, maintenance, trainings and sterility.

The LUMC executive board has to prioritize budget requests as there are always more requests
than there is budget. The board makes the priority list on basis of the strategic plan of the LUMC, discussions
with the division heads and the budgeting form.

The board of division 3 of the LUMC already makes their own priority list of B and C type investments.
This is done on basis of the budget form and on an advice commission existing out of department heads.
This approach is developed to increase the acceptance of decisions within the diverse division.

For investments below € 10k (type X investments) and between € 10k and € 100k (type
B investments) the budget is not actually requested. Each year the executive board distributes lump sum
budgets to each department in the LUMC. The executive board determines these budgets on previous
budget allocations and on the available budget. The departments themselves manage these lump sum
budgets. So the decision to use a budget is taken in the department.
There are five issues with the current budgeting system that have an effect on procurements:  
1. It is possible for a department to place a budget request in a investment type category by lowering the annual budget by spreading the investment over a few years  
2. A large budget request by several departments can be placed in a different investment type category by spreading the budget over the departments  
3. Producers provide discount to the LUMC to improve their image. As a result the budget request is lowered and can possible by placed in a different investment type category.  
4. Producers provide medical devices for free to the LUMC to improve their image. These devices are not budgeted at all and are not reviewed.  
5. Type X and A investments are budgeted by an annual lump sum per department. As a result the efficiency is less; in general because efficiency of the distribution and of the actual investments is not controlled, specifically because there is a budget run at the end of the year.

Issues 1 to 3 make it possible to lower the investment category for a department. As a result an budget request is not as critically reviewed with a budget form as it is meant by the LUMC regulation. Issue 4 introduces devices into the hospital that were not in competition with other devices, providing a possibility to introduce devices that are not the best choice, if price is ignored. Issue 5 is a trade-off by the LUMC, as it wants to provide the departments with enough flexibility to determine their own strategy and to lower the organizational pressure.
CHAPTER 4. INTERVIEW DATA OF THE PROCUREMENT

This chapter answers sub-question 3. It contains all the details that answer that sub-question.

Sub-question 3: In what way are procurements currently carried out?

First a conceptual framework is made, that is used to guide the presentation of the data in this chapter. Then the different kinds of budget input for a procurement are described (§ 4.2). The conceptual diagram is used to present the four phases in the procurement, which are first, the formation of a procurement group (§ 4.3), second, the specification of the requirements (§ 4.4), third, the selection of a supplier (§ 4.5) and last, the acceptance and payment of the purchase (§ 4.6). After the four phases, data is provided about subjects that influence all phases of the procurement (§ 4.7).

Each part is ended with a summary. In the last paragraph (§ 4.8), sub question 1c is answered.

§ 4.1 Guiding framework for the presentation of the procurement

The conceptual framework that is used in this chapter to present the way procurements are carried out is inspired by discussions of past procurements during the interviews. The framework is not extensive and only meant to guide the description of the procurement. Now follows the description.

After the budget request is granted, the requestor of the budget will start up the procurement. The requestor has to determine whose help he needs to procure a medical device successfully. The first step after the budget is granted is therefore the formation of a procurement team. If the requestor does not need help, he or she is the only team member. The requestor can also decide to assign someone else as the leader of the procurement.

With this procurement team one can start to specify requirements what is needed. Different things can be investigated for that, such as the products on the market, requirements of users, risks analyses, technical requirements. In the end it will result in some kind of program of requirements, be it only in the head of the one who needs a device, be it in a formal document to be used in a tender.

The specification of requirements will then lead to a search for the product that meets the requirements. This search can lead to an order of a standard item, or the outcome of a European tender. The supplier selection can have very different forms.

This medical device will then be tested, if it meets the requirements. These tests will be different for the different types of procurements that are made. These tests try to confirm that the product performs as is required and as is described in the manual. Only after the acceptance test it is paid.

These four steps (figure 4.1) are described and summarized in the coming paragraphs. It is not a chronological description of what is done in these steps, but a discussion of issues that are relevant in these steps. Every step is summarized after the description of the step. The last paragraph of this chapter, § 4.8, provides the answer to sub-question 3.
§ 4.2 The input of a procurement

There are three different kinds of inputs for the procurement. The first one is described in the previous chapter, the budget process. The second one is the gifts to the LUMC. The third one is the procurements that are paid (afterwards) by the insurance system.

§ 4.2.1 The budget outcome: lump sums and B and C investments

As described in § 3.4, the budgeting process ends in specific budgets for B and C investments and lump sums for the divisions to spend on X and A investments. These two distinct budget processes lead to the start of two different procurements of medical devices. For X and A investments the procurement is low profile, probably only in one department. For B and C investments, the procurement is known amongst different actors that saw the budget form.

Regularly, budget requests do not lead to procurements, because the requestor does not start a procurement process for reasons unknown. It is not clear if this only happens for X and A investments, or also for B and C investments.

§ 4.2.2 Gifts not part of a procurement, but are part of the solution

Medical devices that are given are not part of a procurement process ‘by definition’. It is not procured, but given. If research boundary number 5 (focus on procurement) is taken strictly, the gifts will not be part of this research. But research boundary 3 defines that gifts are part of this research. As the gifts are not part of the budget or the procurement, it is not guaranteed that anyone checks these gifts carefully. They potentially pose a bigger threat on patient safety because of that. As patient safety is the main issue for the board of the LUMC to start this research, it is of importance for this problem owner that something is done with it. The gifts are not part of the description of the procurement below. They are however part of the problem and should be solved. There is one phase in the procurement of which gifts of active medical devices are part. And that is the acceptance test by the clinical technology department at the end of the process.

Only a few interviewees mentioned given devices as a potential threat to safety.

§ 4.2.3 Medical devices paid by the insurance system

And there is yet another category of devices that is not paid for with the budget system. These are the medical devices that are procured for specifically one patient. One can think of prostheses of knees or shoulders, pacemakers and cochlear implants. These goods are paid by the insurance system, which is a different source of budget.

§ 4.3 Phase 1: The formation of a procurement team

In this paragraph the first step of the framework of figure 4.1 is presented, the formation of a procurement team. This describes who leads the process, and how it is determined who is part of the
procurement team and how they are part of the procurement team. It will start with definitions that are used in this chapter, and the regulation that is identified in the interviews.

§ 4.3.1 Definition of user, procurement leader, requestor, and project leader

During the interviews the terms user, project leader, procurement leader and requestor were used as interchangeable names for it seems the same person; the person who is directly responsible for a successful procurement. If this is a division manager, this is by no means an actual user. The requestor of a budget request for a new device also does not have to be the user, it may well be its manager. From now on in this research these are defined as follows:

- **User**: the one actually using the medical device for medical procedures
- **Procurement leader**: the one leading the procurement
- **Requestor**: the one that requested the budget for a procurement
- **Project leader** is not used, as it is too vague

§ 4.3.2 The regulation for a procurement

The only distinctions that are present for the procurements are:

1. Above a € 50k budget, the purchase department must be involved in the procurement
2. Above a € 250k budget, a European tender has to be put out

The purchase department has two measures it can use for procurements:

1. Sign all procurements that are above € 10k. This gives them the opportunity to ask questions if the purchase employee sees something unexpected. But this measure is limited, as the purchase department has no in dept knowledge about medicine or medical devices, while the department that puts an order in FLITS does have authority.
2. Decide when a European tender will be put out. This gives them the power to hold a procurement within the hospital until they think the tender is good.

Other regulation that is present is for tests performed by the facilitating departments.

1. An active medical device has to go through a release procedure performed by the clinical technology department.
2. Decontamination devices are tested on the adequacy of the cleaning process by the sterility department.

§ 4.3.3 Involvement of facilitating departments

For procurements it can be of great importance to involve facilitating departments, as they have a higher knowledge level on their specific terrain. To date, the formation of the procurement team is always re-invented with each procurement, without any formal feedback from accomplished procurements. It is up to the procurement leader to involve facilitating departments.

The formation is crucial for a successful procurement. All facilitating departments are aware about all decisions of budget type B and C by the budgeting form. Although they are involved in the budget phase by the budget form, it does not guarantee that they are involved in the procurement of B and C investments. And although the facilitating departments are aware about B and C investments, they are
not about the A and X investments. This raises the question how the facilitating departments involve themselves in procurements. This is how each facilitating department tries to be involved:

**Clinical technology**

If the device is accepted it will be paid for using FLITS. Clinical technology just became able to watch purchases in FLITS. This is their first possibility to be involved in a process they were not aware of, but in which they should have been involved according to their own judgment. Currently the clinical technology department does not have the power to stop an order in FLITS. It has to go to the project leader and convince them to change the procurement. This moment in which the clinical technology department can judge if they need to be involved is too late in the process, as it is very inefficient to change a process that is in this stage.

**ICT**

ICT is never directly involved, but always asked by clinical technology. It is up to clinical technology to judge if their knowledge is not sufficient to give a good advice. As there are no clear agreements made between ICT and clinical technology, it is up to the interpretation of the staff from clinical technology if a certain procurement requires the ICT department. This has lead to an interpretation problem with telemetric for cardiology, as the knowledge of clinical technology was not sufficient to foresee a problem. It turned out that the infrastructural assumptions for the telemetric device made by the producer about the LUMC network were wrong, which required a complete new design before the product could be used. This problem could only been foreseen by experts of the ICT department.

So currently the interpretation approach is not working, as there are no agreements between the two departments, nor is there enough knowledge at clinical technology present to interpret the involvement of the ICT department well. There the ICT was called when the device was in use.

ICT writes protocols that a device has to meet if it wants to make use of the network. Indirectly ICT involve themselves in purchases by setting standards on the infrastructure of ICT networks. This does require the project leader to know and understand these standards.

**Infra**

Infra has a meeting every six weeks with the division boards individually. In these meetings the list of construction work is prioritized. The meetings gives infra a good insight into what infra demands are coming and what is on hold and what is cancelled. Of course not all changes are necessary for the placement of new medical devices, but a part is.

All construction work has to be coordinated by infra. Infra uses white coupons (witte bon) as an administrative instrument. Without a ‘white coupon’ it is impossible to do any construction work, as no one but infra is allowed to change the building.

**Purchase department**

As is mentioned above, the purchase department should be involved in purchase above € 50k. They provide contracting knowledge and will try to make the user aware of the trade offs that are present between price and quality. With a European tender this is especially important.

Next to the official obligation to involve the purchase department above € 50k, the purchase department has a quarterly meeting with the division boards. In these meetings the status of ongoing procurements, the coming procurements, which procurements are on hold and which ones are cancelled is discussed. This information is used to sent staff of the purchase department to the project leaders in the departments. This is a proactive approach, chosen by the purchase department head to better profile his department and its added value in the hospital.
Radiation hygiene

A radiation hygiene expert is by law required to be involved in any purchase for medical devices that emit ionizing radiation. By law it is required that the operator of such a device has taken all precautions to prevent unnecessary radiation to patient and personnel. For this, it is required that the user has proven skills and a valid certificate to operate the medical device. The necessary precautions and the training should be implemented in the program of requirements.

It is the responsibility of the radiation hygiene expert to guarantee that this is all thought of before the device is in use. In practice, the radiology department manages the largest part of the radiating devices. It is the task of the radiation hygiene expert to check if all protocols are implemented and followed.

An unaddressed issue concerns non-ionizing radiating devices, or lasers. These devices need certified and qualified personnel in order to be operated safely and also need precautions to avoid unnecessary exposure to patient and personnel. Nevertheless, these requirements are neither required by law and nor supported by the LUMC board.

Sterility

The sterility department greatest concerns are with the devices that decontaminate medical devices, with the procedures for decontaminating the medical devices and with the decontamination devices. The disposables that come into the hospital are already packed sterile complaint with European regulation and do not need special attention. In procurements for medical devices, the sterility expert is little involved.

The sterility expert is involved in procurements of decontamination devices. During procurements of decontamination devices, the sterility expert tests how effective a device decontaminates by cultivating samples of a decontaminated device.

The sterility expert has a binding advice about the use of a medical device and on contaminating devices, if these do not perform according to the norms. This is limited to the use of a device: it is still possible to procure a device with an advice not to use it.

§ 4.3.4 Summary formation of procurement team

It has not become clear how and when it is determined who becomes the project leader, nor how the project leader forms a procurement team. There is no protocol or procedure for this in place.

There is regulation that stems when the purchase department should be involved above € 50k, that clinical technology should test active medical devices and that the adequate functioning of the combination of a decontamination device with a reusable medical device should be verified.

What is seen is that all facilitating departments try to involve themselves via different ways, like quarterly meetings, information from another formal function, or via FLITS.

§ 4.4 Phase 2: Specification of requirements

In this paragraph the second step of the framework of figure 4.1 is presented, the specification of requirements. This describes how the procurement team comes to a formation of a program of
requirements. The emphasis in this phase will lay on internal discussions about requirements, with in mind the limitations of the currently available medical devices. It will start with the description of a standard list that is in use, and then it will describe a device classification scheme that could provide the procurement team with an idea of the importance of a good program of requirements. Then it is presented how the interviewees think about a risk assessment and what at this moment is the largest risk for patient safety in hospitals. It ends with a description of the program of requirements.

§ 4.4.1 Standard list of procurements

The current procurement payment system FLITS (§ 4.6.2) has a standard list of items. These standard items are advised by the purchase department whenever someone orders the same type medical device, but from a different producer. Currently the standard list is not judged on safety of the device in the hospital, as became clear after a discussion of the FLITS manager. Neither is the standard list reviewed frequently to remove old items or obsolete items.

Fewer items are standard since FLITS is introduced (2005) compared with the old system. In the old order system before the introduction of FLITS, 60% were predefined goods and 40% was open. Now with FLITS, 25% are predefined goods and 75% is open.

A standard item does not remove the necessity to specify requirements, as it needs to be determined if the standard item could deliver a certain function. It does remove the phase to select a supplier. Furthermore it improves the standardization in the hospital, with all kinds of benefits for maintenance, discounts and trainings. The purchase department is active in the standardization.

§ 4.4.2 Device classification

All devices are distributed in an internally used and developed risk classification scheme. The classification of active medical devices is done once by the department clinical technology in 2004. This is based on a NIAZ project in 2004. There are three risk classes defined for medical devices, high medium and low. Relevant criteria are the number of users of the device, the frequency it is being used, costs of ownership and the life cycle of the device. The scoring system is device specific and location independent. This is used by clinical technology towards the user to make him more aware of the risks, and to think of actions to mitigate the risk or the potential hazard. This will have its effect on the specification of requirements. For B and C investments it is asked in the budget form what the risk class is. For X and A investments this question is never formally asked in the process.

There are two flaws with this classification system. Firstly, it is sensitive to the user classifying a device and, secondly, it is never updated, making it vulnerable for new and evolved technologies.

§ 4.4.3 Risk assessment

As the risk classification is somewhat outdated (from 2004), the interviewees were asked about the possibility of risk analyses in the procurement process. The aim would be to identify possible risks during use, with the user context in mind.

It is thought that the LUMC has all the capacity present needed to perform good risk assessments of devices that are procured. But that capacity is spread throughout the hospital and does not come together when that is needed. And personnel might not be aware of risks either. Regarding instrumental services, the department seems to be qualified to assess risks, as that is the task of the clinical physicist who
should be present at that department\textsuperscript{11}. For radiation devices, the radiation hygiene staff can advise the procurement team. It is hard to determine if all the right knowledge is present, but if it is detected that knowledge is missing, it is financially no problem to consult external experts like TNO. It is the task of a procurement leader, supported by his project team, to identify missing knowledge. For procurement leaders it is hard to distinguish between infra, instrumental services and ICT. It is up to these three departments to clearly communicate with another so that the right problem owner does the work.

Some users notice a trend towards risks analysis, in the sense that it is something not time effective in its current form, the bureaucracy that it comes with is enormous.

The visibility of risks in all kinds of investments might be improved, also for the passive medical devices in the hospital and not only for active devices medical devices. At the moment risks are not really part of budget decisions or procurements and so it is not taken in consideration.

\textbf{§ 4.4.4 Medical device procurements with largest risk for patients}

Most interviewees from the facilitating departments are of opinion that the largest risk for patient safety is coming from the budget investments they are not involved in, the type A and X investments. If it is true or not is not debated here, but it is seen that large investments (A type) also introduced potential sources of hazard to both personnel and patients. Examples include the syringe pump and hospital bed projects. Both projects did involve facilitating departments, but both procurements formed a direct threat for the safety of patients (pump) or staff and patient (bed) and both experienced operational imperfections when being taken into use (see § F.1 and § F.2 for more details).

\textbf{§ 4.4.5 Requirements specification}

The requirements specification or program of requirements (Programma van Eisen) is a document that is used for at least the tenders by the LUMC to evenly communicate to all suppliers and producers what the requirements for the device are. This document will contain so called knock-out criteria (criteria that have to be met), criteria that must meet certain minimum or maximum or range values, must be capable of meeting prescribes procedures and so on. For European tenders the document will also contain the algorithm that selects the winning bid.

Sometimes a user test is also a criterion. A problem with that is that it is hard to prove user specific opinions, as they are most often subjective.

Regarding ionizing radiation devices, confidence exists that the LUMC is well capable of developing a program, as it possesses all knowledge about the radiology devices; technically and clinically. Furthermore, inside-knowledge is available about what the user demands for functions and how the user works. On the radiology department programs are created in team, and by consulting users whenever it is required.

The Radiology Department also procures radiating radiology devices for other departments. For this, the user is asked what he requires, and this information is used to specify user, technical and clinical requirements.

In the cardiology department, the department’s clinical physicist has a leading role in procurements. He is the one that asks the users their side of the requirements of a device.

\textsuperscript{11} At the moment of the interview personnel changes were ongoing. It was not clear if there is going to be a clinical physicist present in the future.
§ 4.4.6 Summary of specification of requirements

The LUMC uses a standard list of items that a user can use to procure an item. This standard list still requires a program of requirements, as it is necessary to determine if the standard item complies with the requirements.

The LUMC has made its own risk classification scheme in 2004. It is developed for the classification of active medical devices. It is a first start of a classification scheme and it is not perfect at the moment. It is not updated, and the outcome is partly dependent on the person who is classifying.

The interviewees were asked about their opinion about risk assessment in general. At the moment it is not in use in the procurement to improve a program of requirements. The interviewees from the facilitating departments believe that the LUMC has all the expertise to perform this in-house, although all the necessary knowledge is scattered throughout the organization.

All interviewees who had an opinion about risky investments, pointed towards the X and A investments as the investment with the highest risk, as there is no one controlling the procurement leader. It is true that the type A and X investments can lead to risks for patient or personnel, but the involvement of staff departments does not exclude this possibility either, as is proven with the beds and syringe pumps.

The last paragraph discussed the actual formation of the program of requirements. During all interviews it became clear that these are formed for the procurements that required a European tender. Not one time is a program of requirements mentioned for smaller procurements. This does not exclude that it is made, but it is something to note here.

§ 4.5 Phase 3: Selection of supplier

In this paragraph the third step of the framework of figure 4.1 is presented, the selection of a supplier. This is presented for the large European tender, and for the smaller procurements. Also a description of user tests is described here.

§ 4.5.1 European Tender

A European tender is a tender that is open to all suppliers and producers with CE certified devices. By law a hospital in the Netherlands is not allowed to operate a medical device that is not CE certified. The tender is started by announcing it in public and an invitation for a presentation about the tender. The European tender is a tender in which the selection formula needs to be published at the same time as the requirements specification. It is not allowed to change the selection formula or the program of requirements. It is allowed to give answers to questions of producers of suppliers, but the question and answers should be made available to all that apply to the tender.

After all the bids are collected from all bidders, the selection formula provides the answer to who wins the tender. If the release procedure is accomplished successfully, then the tender can be finished with a contract between LUMC and producer or supplier.
In the syringe pump project, the sensitivity of weighting criteria in the formula for the selection of a supplier was not tested. Thus, a supplier with limited experience with syringe pumps won the tender (Koornneef, 2008).

If a product is unique, but above € 250k, the board will grant an exemption for a tender.

User tests needs to be carefully designed in order to avoid subjectivity in judgment if they need to play a role as selection in a European tender. It requires a lot of organization, and then it still might remain a subjective opinion of the users testing the device. This subjectivity makes it hard to use it as a formal criterion.

In some cases it makes sense to maintain a certain medical device line (MRI or X-ray for example) from one manufacturer, as the diversity in the control panels is too different between the brands. A European tender then becomes a challenge to specify towards a certain supplier. Sometimes it still leads to another outcome, which then must be accepted.

The image of the purchase department is that of a department that slows down a process. But this department is convinced that it can start and finish a European tender within 50 days, as long as the user knows exactly what he or she wants.

§ 4.5.2 Selection of supplier for investments below the European tender border of € 250k

Little was discussed about the selection of suppliers for the smaller investment types X and A, the B investments below € 250k and gifts. For instance, one example is about a coagulate time indicator, which was procured by looking for what is one the market. When placing the order for the selected product into FLITS, it became apparent that the preferred product turned out to be a standard item in FLITS. Here, the formation of requirements is performed with help of a market research.

Another example regards cochlear implants, which are financed via the insurance system. One implant costs about € 25k. The medical specialist procures this device based on measurements taken from patients. In consultation with his audio experts who know in detail how these devices work, the doctor then determines the preferred implant for a specific patient. There are a few market parties from who they can select from to procure a cochlear implant.

§ 4.5.3 User test

User tests can be a part of the selection of the proper supplier. These user tests are not performed for every procurement, as it is time consuming, and not useful for every procurement.

User tests were done for several syringe pumps, new beds, and for suture. For the syringe pumps, the user test was performed by testing several different pumps. Nursing staff first received a short training, and right after that tested the device with the supplier present. Then the nursing staff filled in a form to motivate their opinion about the pump.

For the bed it is discovered that after the user test, additional requirements were formulated. These requirements were implemented, but never tested again. In general the requirements specification is formulated with only a few people involved. Sometimes the user will come with additional requirements, after the program of requirements is finalized and distributed to all potential suppliers. Typically, these products are then not again tested by an acceptance test. This brings in the possibility of accepting a product with errors, as was the case with the procurement of new beds.

For suture, a test program is developed to test the suture from the selected supplier. The suture is introduced on the operating theatres and will be used by the less ‘delicate’ disciplines, which is about 80
\% of the surgeries. Depending on the opinion of the doctors after the learning and experience phases, will it be determined if the new suture will actually be procured. It will be hard to turn down the offer of the producer by the outcome of the user test, because it are subjective opinions of doctors, which is hard to use in a legal dispute. Note that in this example not only the suture is being tested, but also the surgeons who learn how the new suture should be used.

§ 4.5.4 Summary of selection of a supplier

If the amount is above € 250k the selection of suppliers should be done by a European tender, unless the product that is wanted is unique. A European tender consists out of a program of requirements, contract details and the selection formula to select the winning offer. The selection formula in the syringe pump project was not tested adequately.

For procurements that do not have to be procured with a European tender, very little is known how the internal procedures are. One example is a procurement of a coagulate time indicator, that was procured by looking what was on the market and could perform the required function. Another example of cochlear implants showed that these are procured with attention for every unique patient, by staff that knows how the implants work.

User tests are a new phenomenon in the LUMC. It is not performed for every procurement, because it is a process that costs time and money. The user test for syringe pumps was not thorough, as it did not test the different syringes in critical tasks embedded in the requirements specification. The new beds also had a user test, but after the user test additional changes were requested, which were not tested after being installed. The suture is tested for a long period, and by asking user about their experiences. It is thought to be hard to decline an offer with the subjective preferences and opinions of doctors.

§ 4.6 Phase 4: Acceptation and payment

In this paragraph the fourth step of the framework of figure 4.1 is presented, acceptation tests and the payment. This last step in the process describes how the LUMC verifies what is procured and if it complies, as well as how the supplier then is paid.

§ 4.6.1 Release procedure

The release procedure is a procedure carried out by the clinical technology department after an active medical device is received by the LUMC and before it is taken into use in clinical care or in trainings. The release procedure is only performed for medical devices that use an electrical source of energy. This group is called active medical devices (§ 2.1). The sterile disposable devices are only checked if there is a problem reported with them.

The clinical technology department will test the medical device on technical aspects. These aspects are tested with use of the manual and the technical requirements in the requirements specification. If the device complies, it will be labeled and transported to the user who needs it. If a large group of devices comes into the hospital, a sample will be tested.
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The clinical technology department is not authorized to deny a user its device, but may not sign a release form if it is known that the user is not educated for a device that needs education. There is no formal check in the release procedure to the education level and requirements.

A user assumes that these acceptance tests in the release procedure delivers a device that is safe to use, as it is tested by clinical technology department. For the user, it is hard to have a skeptical look at devices when they perform as required, as this would hamper the work speed.

Regarding acceptance tests, the LUMC should better check if what is bought is actually what was requested in the requirements specification. This requires more extensive tests than are currently used in the LUMC. The clinical technology department mostly tests on electrical requirements.

§ 4.6.2 The payment system FLITS

After or just before the acceptance test in the release procedure, a product is paid with FLITS.

In 2005, Oracle delivered their PeopleSoft ICT infrastructure to the LUMC. It was called FLITS, which stands for Financieel, Logistiek, Inkoop en Projectmanagement (Finance, Logistics, Purchase and Project Management). The LUMC directorate Finance started the project, in order to improve their information supply on diversity, frequency and accuracy from processes of logistics and purchases. This improved the operational management capabilities for the LUMC executive top of the organization. For purchases, FLITS would provide a standard list of possible product purchases that might be made by the hospital personnel (Oracle, 2007).

Only the functions used in the procurement are mentioned here. The other functions of FLITS are not relevant for this research and therefore not studied. Currently, the purchase department uses FLITS to collect bills. FLITS provide the user with a computer interface in which it is possible to insert payment request at a local level. All these payment requests are processed and paid by the purchase department. The purchase department holds a signing authority above €10,000, which means that this department must sign a purchase above that amount, together with the responsible initiator of that purchase.

The clinical department uses FLITS to monitor which purchases are filed. This way, the department might identify procurements in which the clinical technology department should have been involved, but were not. In such a case, the purchase order is screened in order to improve the overall safety, by looking at missing maintenance contracts, and by assessing whether the procurer had enough knowledge to judge its own procurement. The clinical technology department has no authorization for stopping procurements that are not done properly. It might be best for the clinical technology department and the LUMC if the current reactive approach is changed towards a proactive approach.

An important problem with FLITS is that many users can order in it, and that low costs purchases are not checked. Another problem with FLITS is that the standard list is not working. Before FLITS 60% of the products were standardized, while with FLITS this is only 25%. It is possible to order anything with FLITS. Maybe the purchase department will start asking questions, but that is unlikely as this department is not adequately knowledgeable to recognize wrong procurements.

Some actors expect that if a product is ordered in FLITS, the purchase department will come with advice to improve the procurement, by proposing different suppliers or producers and by proposing possible similar purchases so that price cuts can be lowered. This expectation is false, as the purchase department has neither the capacity nor the knowledge to give this kind of advice, and FLITS is not intended to be the platform for such advices. Instead, there should be a request of the initiator to the purchase department for advice.
§ 4.6.3 Summary of acceptation and payment

The clinical technology department performs the release procedure with the acceptance test. It only tests the active medical appliances, and only whether technical requirements are met. This is not clear to all users. Medical devices that decontaminate other medical devices are tested by the sterility department on the adequacy of the cleaning process.

FLITS is a system that is used in the procurement to collect orders on a central location coming from a local level. At the central level, the purchase department pays the orders. The purchase department should authorize purchases above € 10k. The department tries to improve standardization, by offering substitutes for certain medical device offers that are comparable in function with a standard item. The purchase department cannot offer a procurement leader to procure a standard item, as the purchase department does not have the proper medical knowledge to judge a procurement on its content.

FLITS is also used by the clinical technology department to monitor the procurements to identify those in which they should have been involved, but were not. With this approach, the department hopes to lower the number of procurements that will lead to unsafe situations. The clinical technology department acknowledges that this is a reactive approach.

§ 4.7 All phases: Subjects of influence on the whole procurement

In this paragraph subjects influencing all the steps of the framework of figure 4.1 are presented. These general subjects are therefore not logically connected to each other or a process phase. This paragraph describes a commission active in improving quality issues surrounding medical devices. Then it describes the wish of the user regarding the procurement process, as well as the wish from the facilitating departments about how they expect the user to act. Special attention is given to the expected role of the purchase department and of its assortment coordinator.

§ 4.7.1 Central Material Commission (CMC)

The CMC is defined to be a quality subsystem by the executive board, which makes it a part of the quality management system, as defined in its founding documents (LUMC, 2008). The two goals of the CMC are to improve the guaranteed safety of patients related to medical appliances and to improve effectiveness for the whole life cycle of medical appliances. The two instruments the CMC can use for that are writing protocols and checking the compliance of personnel with the protocols. The CMC has no authority to intervene when someone is not working according to the protocol. The primary persons responsible for the compliance with protocols are the department heads and division boards. They are also responsible for the implementation of protocols of the CMC.

In order to make it possible to work effectively, the CMC consists out of four so-called chambers, which are in essence specialized sub-committees. These chambers all have their specialty for different types of materials that are in use:

1. The chamber of sterile and non-sterile medical appliances
2. The chamber to patient connected devices and active implants
3. The chamber laboratory devices and articles, for diagnostic and research purposes  
4. The chamber facilitating articles; meaning all other articles  

The priority of the CMC is the operations of the first two chambers. The heads of the four chambers together with the head of the CMC form the CMC. The first two chambers each have two medical specialists (one is head of the chamber), two nurses, an assortment coordinator, a hospital hygienist, a sterility expert and a clinical physicist that form the chamber.

If the specialties of the first and second chamber are related to Appendix D and § 2.1, it is found that the definition of the Law indicates that the first chamber has a wide specialty, which also contains the specialties of the second chamber. Patient connected devices and active implants (second chamber) are part of sterile and non-sterile medical appliances (first chamber). The founding documents do not give a definition of the specialties of the chambers. This leaves open the possibility of misinterpretation. Furthermore, the founding documents do not substantiate why specifically these four separate specialties for the four chambers are defined.

Functioning of the CMC

Currently, the CMC is not effective, as the responsibility distribution between the CMC and user is unclear. Furthermore, the CMC's power it too limited to fulfill its role. In the future, the CMC might become very useful for determining which devices can and cannot enter the LUMC, based on some kind of risk analysis.

The CMC exists now for 3 years, replacing the local MCs, therefore, to decrease bureaucracy. The CMC is not functioning in improving safety, as the CMC has no authority over the executive core. As a quality subsystem, the CMC is never directly involved. Also, the problem of finding and keeping chairs for the chambers is real. Furthermore, not enough information is provided to the CMC to develop protocols on. As a result the CMC consumes time, while it does not deliver improvements. Although, all this might be true, another chamber of the CMC does develop policies, and also verifies if they are useful, by asking questions to procurement project teams about their procurements. From this point of view, one might say that that chamber is working on an acceptable level, which could very well be improved. The biggest problem for the CMC is that the implementation of protocols is hindered, as the protocols are not actively distributed to the users, but just published on a web page.

Possible future role of the CMC

Interviewees see a role for the CMC to check upon procurements, possibly with the condition that first a good procurement protocol has to be made. Crucial for the success of a procurement is the involvement of the right people. This requires methods that should be followed for procurement, so that the right team is formed for the right procurement. This also solves the problem of the variety of devices that are bought according to the doctors’ wishes alone. The team should at least consist out of enthusiasts and out of critical staff when it is for a large procurement. A commission should check the procurement team its progress. This check should also be used to improve the process and improve the overall safety, by recognizing best practices and learning moments. Members of the CMC argue that the CMC should be more involved in procurements, although its direct role in procurements can only be limited as the CMC meets only ones every two months.
§ 4.7.2 Fear of specialists of useless bureaucracy

When the specialists were asked about there procurements, they were satisfied with the current business. However, they were afraid that this SMS Medical Devices Supply Chain project would lead to extra and useless bureaucracy for their purchases that are now still going fine. This would be unacceptable to them. But they also see the potential benefits of involving other departments to take over a part of their work in the procurement.

The procurement should be better secured and formalized, but dynamically determined by the risk of the procurement. If this would not be done dynamically, it might create too much bureaucracy to work for the LUMC.

§ 4.7.3 Role of purchase department

In general, the purchase department should improve its added value for the rest of the hospital. One experience with the department is that when it is involved, a procurement requires more time, while it does not effect the quality or price of the procurement. Users like to have a purchase department that helps them in procurements. It might be ideal if the purchase department would let the user only worry about the requirements from the user side. This way, the purchase adds value that the purchase department has no clear profile in the organization, and is mainly associated with bureaucracy. To improve this image, the department actively approaches project leaders of procurements. Also, the department would like a more centralized realization of procurements. This would require a prioritization of procurements, as there are many. Furthermore, the department wants to introduce is a system that needs to learn from itself, as it is not known for sure at the moment which procurements need a large procurement team, and which do not.

The actual role of the purchase department in procurements is to market a product request in the best way on the market for the LUMC. The purchase department adds knowledge about formulating tenders and contract, and about the procedure of tenders. With the assortment coordinator the purchase department can help the user to translate its requirements into the contract.

In general, the purchase department is only involved if it is required by internal protocols. The reason is that involving the purchase department involves a lot more people who are not really of help.

A great role for the purchase department might be to scale up purchases, by combining different wishes of the different departments. It is perfect for that because of its central position. It has the great advantage of cost reduction. The disadvantage is, that this does mean the whole procurement takes more time and that different requests have to be combined in one product.

§ 4.7.4 Assortment coordinator

Stated in the formal function description the assortment coordinator has as goal to limit the assortment on basis of user specifications, while keeping the overall quality, safety and effectiveness. For procurements, the assortment coordinator will assist the user to form the requirements specification, to design test procedures and to coordinate and guide the introduction of new devices in the departments. Less close to the procurement, the assortment coordinator should involve himself in the local material committees (the function specification is before the CMC was formed, so now it would be the CMC) to advise on standardization possibilities. To prepare himself to advise in procurements, the assortment
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coordinator has to be up to date with the latest market developments. For that there are several assortment coordinators in the hospital. (LUMC, 1998)

The assortment coordinators are part of the purchase department,. They are and probably cannot be educated well enough to perform the task they formally need to do for all device procurements. They lack the time to be up to date about all market developments, nor are they trained to understand the complicated functioning of all medical devices. And even if they were trained well, the number of assortment coordinators is too low to perform all the tasks that are expected. They are well capable to perform their task for the devices that are available in the hospital in large numbers, like disposables and beds. Knowledge about the more rare devices should be present with the users using it. The assortment coordinator is more capable of formulating user requirements than the clinical technology department is, but this is still limited, as they are not the actual users.

Compared to the clinical technology department, the assortment coordinator looks more at the user aspects while the clinical technology department looks more at the technical aspects in the procurements the department is involved in.

Some people see the assortment coordinator as a “walking encyclopedias” for the organization. They are aware on recent developments on market, and ask the user questions so to form a program of requirements. And because of their knowledge, they should protect the hospital against unwanted devices. The assortment coordinator is not someone who performs risk analyses.

§ 4.7.5 The responsibility of the medical departments

All staff departments are of opinion that the procurement leader and the actual user should act more responsible in any process in the whole life cycle of a medical device in a hospital. In procurements, the project leader is not always involving the staff departments when that was needed, the objectivity towards the functional requirements is lacking, and maintenance contracts are often forgotten. That is why the staff departments try to get involved in the procurement as early as possible by regular meetings with the divisions.

A trend is that more and more the division heads are given a great deal of responsibility. These people are not the ones that have the knowledge to be responsible, as they do not have medical knowledge.

A lot of misunderstanding seems to come from the differences the different experts have. The definitions they use can be interpreted differently. For a highly advanced medical device, this problem is solved because of the small number of enthusiastic experts that involve themselves with the device. But for dedicated devices there is no one who feels responsible.

An improvement might be to have some kind of process supervisor. He or she should control that all steps that are necessary for a successful procurement are made indeed. This supervisor should not be connected to the departments that need the device. For instance, someone from the purchase department or the CMC might have this role, as they do not have a certain preference of a device. Even the clinical technology department has preferences, as it performs maintenance. Such a supervisor should only check all the steps, he or she should not perform these steps themselves as that is up to the procurement team.

§ 4.7.6 Meaning of CE certification

What is tested by CE certification is unclear to most interviewees. One sees it as a check on electrical compliance, others believe that it stands for a product that is safe to be used. Both views are not what it is
in reality. A CE certificate is brought onto a device that complies with European regulations. That includes electrical regulation, but also standards for user interaction and requirements for first line errors. The medical device is tested according to the risk it poses to a patient. The lower the risk, the less strict the test is.

In the end, a CE certificate means that the device is safe to operate as long as it is operated as described by the producer in the manual (appendix § E.2, Decree Medical Appliances). This means that these manuals bound the user, the specialists and nurses of the LUMC, if they do not want to be responsible for possible adverse events with medical devices.

### § 4.7.7 Summary of subjects of influence on the whole procurement

The goals of the CMC are to make the medical device chain more efficient, and to improve the patient safety in relation to the medical devices in the hospital. All interviewees agree the CMC at the least is not functioning optimally. The reason for this might be that the CMC has no power over the users to correct misbehavior, and the users are not aware about the CMC and its protocols. The CMC can speak with the medical division heads about a more stringent implementation of protocols, but this is as far as the CMC can go.

All users of medical devices and the executive board are of opinion that the improvement of procurements should never lead to useless bureaucracy. This leaves in the middle what is seen as useless bureaucracy. Nevertheless, it indicates the need to indicate the necessity of solutions.

The purchase department is seen as a somewhat bureaucratic institute, with little added value for small procurements. The purchase department is aware of this image, and is profiling its added value towards the medical divisions. The purchase department has knowledge about the formation of contract and tenders. This is mostly used in larger procurements.

The assortment coordinator is defined by an internal document to assist the user in formulating the requirements specification, guide the selection and introduction of a medical device. Furthermore, the assortment coordinator should be aware of the latest market developments for medical devices. In practice, their shear number is too low to perform these tasks for all procurements, and they are not intentionally educated to understand the technology behind a medical device. They are capable of specifying user requirements, although this remains limited, as they are not the real users.

All facilitating departments are of opinion that the actual users of medical devices should act more responsible throughout the whole life cycle of medical devices. For procurements, the procurement leader does not consistently involve facilitating departments while he misses the required knowledge. Furthermore, the procurement leader should become more objective towards the functional requirements. Lastly, the maintenance contract is often forgotten, which then becomes a problem for the clinical technology department. An observation from a user is that the procurement leader more and more becomes a manager with no actual knowledge of the medical procedures in which the device will be used. Also, communication is hindered in multi-departmental projects, as the actual meaning of definitions differs between departments.
§ 4.8 Answer to sub-question 3

In § 4.2 it is defined that there are three different budget sources for the procurement:

1. The budget process
   a. Lump sums for X and A investments, under direct control of the departments
   b. Per request allocated budget for B and C investments
2. The insurance system, for medical appliances that specifically for one patient
3. Gifts of suppliers or producers

The part below answers sub-question 3. It uses references from other chapters as well.

Sub-question 3: In what way are procurements currently carried out?

This chapter began with the definition of a conceptual framework that guided the presentation of the data about the procurement. The diagram of the framework (figure 4.1) is repeated here.

Formation of a procurement team

A staff member of the department or division that requires a new medical device leads the procurements. There is no regulation identified that prescribes who should be the procurement leader.

It is found that the formation of a procurement team is not guided by protocols. It is up to the procurement leader to estimate if and which other departments should be involved in the procurement.

The facilitating departments are involved via different channels in the LUMC:

1. The CMC chamber medical appliances (Sterility).
   Via this chamber, oncoming or ongoing purchases of medical appliances are known
2. By viewing in FLITS the list of medical devices (clinical technology)
   The clinical technology department uses FLITS to identify procurements in which it should have been involved as the current FLITS request is not acceptable to them.
3. By frequent meetings with the medical division boards (infra, purchase departments)
   Infra meets the division board once in six weeks, in which it discusses all infrastructural project, including those required for medical device procurements
4. By the knowledge of the budget form that a procurement is oncoming
   All facilitating departments are involved in answering the question in the budget form. Via the form they are knowledgeable about B and C investment requests. With this information they can decide to approach the user about the actual procurement.
5. By a judgment of the clinical technology (ICT)
   If the clinical technology department is of opinion that its knowledge is not sufficient to answer ICT related questions, they will consult ICT
6. As a requirement by a protocol (Radiation hygiene, purchase department)
The purchase department should be involved in procurements above € 50k. The radiating hygiene expert should be involved in procurements of radiating ionizing medical devices.

The first four points describe processes in which the facilitating departments actively approach the procurement leader. This is no guarantee that they are involved when the formation is ongoing. It is more likely that they involve themselves in the other steps. The use of FLITS actually guarantees the opposite; that clinical technology involves itself at the end of the procurement.

Point five is not a procedure that is capable of guaranteeing an introduction of ICT when their expertise is needed. That it does not work is proven by the procurement of telemetric devices for ICT and neonatology, which is presented in § F.10 and § F.11.

Point six prescribes regulation. It is found that the purchase department should be involved in a procurement above € 50k. In reality the purchase department experience that the medical departments not always comply with this rule. Medical departments have indicated that they have little trust in the added value of the purchase departments for the small procurements. The central radiation hygiene expert checks if all the protocols for radiation hygiene are in use. He should be involved in procurements, but most of the times a local radiation hygiene expert of radiology is mandated for it.

**Specification of requirements**

For the specification of requirements no protocol was identified that guides the process. This leaves open how that the specification of requirements is performed. Two examples of small procurements (X or A type investment) were identified. The first indicated that the specification of requirements was done mainly on what is provided on the market. The second indicated that the specification of requirements was done mainly based on what the patient needed.

With in mind the safety of patients, it was asked what kind of risk assessments were done. These are currently not performed in the LUMC in the procurement phase. There is a classification in the hospital present that classifies device types in a low, medium or high class. It obliged in the budget to answer this question. The budget form is only applicable for the B and C investments, which leaves open all other procurements. The standard list of items within the payment system FLITS is also not designed with in mind the risk a medical device can pose to patients. Both the standard list and the internal classification system of devices are not updated. It was planned to update the internal risk classification scheme annually, which is not done currently.

One interviewee particularly was against a risk assessment, as it is time consuming. Instead, only medical devices are being procured, which hare used daily and of which is known how they technically and clinically work. Another interviewee indicated that help of facilitating departments is not needed for the medical devices used for research, as the department is more than capable of procuring items.

A last finding in this phase was that interviewees are of opinion that the procurement of small devices (investments of type X and A), as there is no control how to develop a requirements specification. It is proven by the procurement of beds and syringe pumps (§ F.2) that the involvement of facilitating departments does not guarantee that the procurement of a device that is safe for patients.

**Selection of supplier**

As defined by internal regulation, procurements above € 250k should be marketed with a European wide tender. The tender form consists out of the program of requirements, and the selection algorithm
that determines the influence of each requirement. It is not allowed to change the selection formula after
the marketing of the tender. For European tender the purchase department is involved to market the
request in the most optimal way for the LUMC. This requires a thorough testing of the selection algorithm.
At the moment the selection algorithm are not tested for the European tenders.

For procurements below € 250k it is unclear how the selection of a supplier is done. Two examples of
procurements of X and an A type investment indicate that it differs on what is bought. The X type
investment of a coagulate time indicator was done by looking at ones needs, and what was available on
the market. It then turned out that the preferred product was part of the standard list. For the procurement
of cochlear implants it investigated what the patient needs. Then this is compared with what is on the
market. What is available on the market is well known by that department.

User tests are another or additional step that makes it possible to differentiate and select suppliers.
User tests are not done for the smaller procurements, but are becoming more important for the larger
procurements of the B and C type investment. At the moment it is still a step that is under development
and requires improvements. It is still not known how it can be used as a strong selection procedure
(suture), nor was it capable in two procurements (beds, syringe pump) of identifying unwanted functions.

Acceptance test and payment

It has not become if all purchases are first paid for and then tested, or vice versa. It is assumed here
that both forms exist in the LUMC.

The acceptance tests for active medical devices are performed by the clinical technology department
that tests the devices on technological requirements coming from norms, the manual and the
requirements specification. It does not test whether the device is acceptable for its user environment. One
user assumed that if it is tested by clinical technology, it is safe to use for the user. Even the gifts have to
be checked by the clinical technology department before it allowed to use it. The devices that
decontaminate other medical devices are tested on its proper functioning by the sterility expert. No test
was discovered for devices that are not active medical devices, or decontaminating medical devices.

The payment is performed by FLITS. In the eyes of some interviewees, too many users are allowed to
use FLITS to order medical devices. FLITS is used to maintain a standard list, and by clinical technology
to monitor procurements. It is only designed to manage the local payment requests on a central location.
The purchase department manages FLITS, and has to sign purchases above € 10k. The purchase
department will suggest users to procure items that are on the standard list, only if the items are
comparable. The purchase department does not have the knowledge to judge if the standard item is
sufficient, that is up to the user.

Items of influence on all phases

The items that are of influence on all the phases as defined in the framework are summarized here. The
CMC is a 3 year old commission, with the two goals of the CMC are to improve the guaranteed safety of
patients related to medical appliances and to improve effectiveness for the whole life-cycle of medical
appliances. It seems the CMC its goal is closely related to the research problem. The two instruments the
CMC can use, are writing protocols and checking the compliance of personnel with the protocols. In order
to improve effectiveness, four chambers are erected with their own specialties:

1. The chamber of sterile and non-sterile medical appliances
2. The chamber to patient connected devices and active implants
3. The chamber laboratory devices and articles, for diagnostic and research purposes
4. The chamber facilitating articles; meaning all other articles

Of the four chambers, only the first two are active at this moment. If the working fields of the first two chambers is related to Appendix D and § 2.1, it is found that the definition of the Law indicates that the second chamber covers a part of what is part of the first chamber. As the founding document of the CMC does not contain a definition of the specialties, it is not clear why specifically these four chambers have been distinguished.

At the moment, the CMC does not function as it should. Various reasons were named. Summarized, the proclaimed main cause the CMC is not functioning is that the authority that is required to meet its goals is only partly at the CMC, while the other part is at the user. It is not researched why the user is not motivated. As the user is currently not motivated to implement the protocols, the CMC cannot meet its goals. And that is not motivating the CMC heads to spend the required time and effort in the CMC either.

The purchase department is required to be involved in procurements above €50k. The purchase department adds knowledge about formulating tenders and contract, and about the procedure of tenders. It is found that users are not willing to involve the purchase department all the time as its added knowledge is limited, sometimes even slowing the process, especially for procurements that are specialties of the departments themselves.

Stated in the formal function description the assortment coordinator has as goal to limit the assortment on basis of user specifications, while keeping the overall quality, safety and effectiveness. For procurements, the assortment coordinator will assist the user to form the program of requirements, design a test procedure and coordinates and guides the introduction of new devices in the departments. This description is not in relation to the actual role the assortment coordinator plays, mainly because there sheer number and knowledge level is not sufficient to perform this task for all procurements in the hospital.

All interviewees from the facilitating departments are of opinion that procurement leaders and users should act more responsible in every part of the life cycle of a medical device, and become aware of the risks of devices. For procurements it is suggested that the cause of less attention for risks stems from the fact that more and more managers become procurement leader, instead of doctors. A last suggestion was to install supervision on procurements to control that all necessary steps for a good procurement are actually performed. This suggests that supervision currently is not common.
CHAPTER 5. WHAT SHOULD BE IMPROVED?

This chapter provides the answer to:

Sub-question 4: What should be improved in the current way procurements are carried out?

This is answered by comparing sub-question 2 with sub-question 3. These were:

Sub-question 2: What is seen as a qualitative good procurement?
Sub-question 3: In what way are procurements currently carried out?

The comparison is lead by the answer to sub-question 2. Per relevant norm of NIAZ stated in table 2.6 a comparison with the present procurement process as described in the answer to sub-question 3 (§ 4.8) is given. As the performance indicators from the NVKF (table 2.7) are closely related with the norms, these are grouped with the norms where possible.

The comparison starts with the question if regulation for procurements is present (§ 5.1). The second question is a risk analysis is performed by the hospital (§ 5.2). Remember that present for NIAZ means it should also be in use. The answers to these questions are summarized in § 5.3. To answer sub-question 4, it is necessary to choose between the areas that require improvement. That is presented in § 5.4.

This chapter marks the end of part 1 of this report and starts part 2; the design of an advice.

§ 5.1 Is regulation for procurements present?

The NIAZ criterion 411.01 specifies that regulation for procurements of all kinds of goods must be present. This includes the procurement for medical devices. The regulation should specify two points:

1. [411.01a] The way that experienced employees are involved in the selection process, if the procurement is for goods or devices used in the healthcare processes
2. [411.01b] The way in which the selection and judgement of the suppliers of goods is carried out

These two points stand in close relation with the operational parameter of the NVKF for budgeting, procurements and introduction; “Percentage of the medical devices taken in use last year that is purchased (...) conform a predetermined procurement (...) process”\textsuperscript{12}.

The two points of the NIAZ are now discussed below, to answer if criterion 411.01 is present. The operational parameter of the NVKF cannot be answered, as this research is not qualitative in nature.

§ 5.1.1 The way that experienced employees are involved in the selection process

This norm 411.01a begs for the question what the NIAZ sees as “selection process”, and were it is visible in this research. There is no clearly described definition available in any NIAZ documentation of what the “selection process” is. Literally translated, this is the part of the procurement in which a supplier is selected. Then one should ask what is required for a selection process. And that is a process in which requirements for a medical device are formulated.

\textsuperscript{12} The brackets in the operationalized parameter of the NVKF indicate parts that are not relevant for this research, as it focused on procurements.
As the NIAZ criterion 411.01 requires regulation to be present, here the regulation that defines how criterion 411.01a is arranged should provide the answer. If one uses the conceptual figure 4.1 from Chapter 4, this is answered with part 1 ‘formation of procurement team’. The ‘formation of a procurement team’ is a part in which the emphasis is put on the actors and process that are needed for the procurement. As the ‘formation of a procurement team’ is the phase in which it is determined who is included in the procurement team, this phase provides the answer if the experienced employees are included in the selection. Two assumptions are made here, to make it possible to investigate the presence of criterion 411.01a:

- The specification of requirements (phase 2 in diagram figure 4.1) is also an important part in the selection of a supplier, as it is important input for the selection.
- The facilitating departments (including ICT and the purchase department) and the users of medical devices (including nurses, doctors, surgeons, specialists, anaesthetist, clinical physicist that use the device) are assumed to be what the NIAZ refers to as experienced employees. Their expertise is bounded by the specialty they work on.

From § 4.3 and its summary it is found that at the moment the facilitating departments have developed different ways to involve themselves. They are required to involve themselves in the procurement processes, as the procurement leaders, coming from the medical departments, do not involve the facilitating departments when it is actually required, in the eyes of these facilitating departments.

There is regulation present when to include the purchase department (for the whole procurement), the radiation hygiene expert (radiation requirements), the sterility expert (acceptation tests) and clinical technology (acceptation). The regulation of the purchase department and the radiation hygiene expert are relevant for this NIAZ criterion. The regulation for the sterility expert and clinical technology are after the selection of suppliers and thus not relevant for this criterion.

The purchase department experiences they are not always involved in procurements in which they should have been involved. The radiation hygiene expert most of the times mandates a local radiation hygiene expert of radiology to perform its tasks. Radiology is the department buying the majority of ionizing radiation devices for the LUMC. The radiation hygiene expert has not experienced any problem concerned with radiation hygiene.

The other facilitating departments all have their own way of being involved in the specification of requirements, which is a leading input for the selection of a supplier. But there is no regulation that specifies which facilitating departments should be involved in the selection of a supplier for procurements.

There is a budget form present in the budgeting process that does involve the facilitating departments in the B and C type investments. This budget form is not aimed at specifying requirements, not on the selection of suppliers. Furthermore it leaves out all X and A type investments, procurements paid by the insurance system and gifts to the LUMC.

It is concluded from the interviews that there is no regulation in use that defines which facilitating departments should be involved and how they should be involved in the phases of specifying requirements and selection of suppliers. This is finding is strengthened by the fact that the at this moment the facilitating departments use different paths within the LUMC to involve themselves in the procurement processes, so to improve the outcome of the procurement phase.

As the user of medical devices is assumed to be an expert in his own domain, this means the user is the expert that can formulate the clinical requirements for a device. The department they work for bound
their expertise on clinical requirements. Users are more knowledgeable than anyone else in the LUMC for what the clinical requirements should be; what the device should do and should not do to make certain procedures possible.

Sometimes a user also possesses knowledge about the technical requirements of a medical device. This is seen for the users that are active in research that is aimed at procedures that solve disorders with use of technological possibilities. As this situation is rare, the rest of this discussion will assume that the user is only knowledgeable about clinical requirements.

As the wish for a medical device comes from the clinical departments, it seems that the user is per definition involved in the specification of requirements as well, meaning that the specification of clinical requirements is secured without the need for regulation. But that is actually not true for two reasons.

First, the user is not per definition the procurement leader. Especially for the larger procurements it is found that a division operational manager becomes the procurement leader. This is someone who is not required to have clinical expertise, and who is not directly involved in the clinical procedures either. This does require the procurement leader to actively involve the user. And the NIAZ requires there to be regulation describing it. From the interview data no regulation is discovered when or how the user is at this moment involved.

Second, the procurement of an item can be carried out for different departments at once. The assumption is made users as experts for clinical requirements for their own department. A procurement for multiple departments thus requires the involvement of all the departments, in order to guarantee that all departments have a chance to bring in their expertise. From the NIAZ point of view, this requires regulation to be present when a user should be involved phases of specifying requirements or selecting a supplier. During the interviews no indication was found that there is regulation active in the LUMC that indicates the way users should be involved.

Criterion 411.01a was: “the way that experienced employees are involved in the selection process”. The facilitating departments and the users using the medical requirements were assumed to be what the NIAZ refers to as experts. During the interviews there was no indication found that there is regulation in use that indicates the way both the facilitating departments as the users of medical devices should be involved. The acceptations were the purchase department, who is required to be involved above € 50k and the radiation hygiene specialists, who supervises if the requirements guarantee a safe use of radiating ionizing devices.

§ 5.1.2 The way in which the selection and judgement of suppliers of goods is carried out

The NIAZ requires there to be regulation present that describes the way in which the selection and judgement of suppliers of goods is carried out, norm 411.01b. This is comparable with the process that is carried out in phase 3 of the procurement as defined in figure 4.1. Three items were discussed for this phase in Chapter 4, which were the European tender, the procurement of devices below € 250k and user tests. These three items are now discussed.

In European tenders a selection algorithm indicates how each criterion from the program of requirements is valued and what the weight of each criterion is. The purchase department is active in guiding the process of formulating a European tender. And regulation of the requirements for a European tender are indicated to be in use. The content of a European tender, the requirements and the weights of the requirements must come from the users who wish a device. For European tenders it was found that the selection algorithm is not tested thoroughly (§ 4.5.1). Testing an algorithm answers the question if the
way in which criteria are valued and weighted represents what the users wish for, with a correct distribution of the importance of criterion in rank and in proportion to another.

For devices below € 250k there is no clear indication how this is selected and judged (§ 4.5.2). It differs amongst the procurements. There was also no regulation named that indicates a method to be used to select suppliers.

Another method that becomes more and more important for the LUMC is the user tests. Users tests can provide a method to select a supplier. At this moment the user tests are done for some B and C type investments (§ 4.5.3). As this is not fully developed fully yet, it still is hard to use the user tests to (partly) base the judgement of a device on. Users are asked to file in forms to judge the device on. But it is indicated that the subjectivity of the opinions of users make it hard to use their judgement as a selection criterion in the process.

Criterion 411.01b was: “The way in which the selection and judgement of suppliers of goods is carried out”. There are three processes identified in § 4.5 that are relevant for this criterion, which are a European tenders and the selection algorithm, the selection for investments below € 250k, and the user tests. It is seen that the demands of the process and presentation of the European tender is regulated and managed by the purchase department. The selection algorithm however is not thoroughly tests if it represents the preferences of the users with a wish of a device. It has not become clear how in investments below € 250k the supplier is selected, nor was it identified if there is regulation present for it. User tests are an evolving process that is not yet fully developed. The users are asked to judge a device, but it perceived to be hard to use the subjective opinion as a selection criterion. No regulation when and how a user test should be performed was mentioned during the interviews.

§ 5.2 Is regulation for risk analysis aimed at quality during use in use?

The NIAZ criterion 411.02 requires the hospital to have regulation for the process of risk analysis in the beginning of a procurement of medical devices, meant to guarantee the quality during use. This is closely connected to the requirement of the NVKF of a risk analysis, which is operationalized by the indicator “Percentage of the total number of devices / systems in the database that is classified in risk classes based on an applied risk analysis”. This part is only answered in relation to the procurement phase, not for the other phases (budget process, introduction, use). This is not answered, as it is a qualitative and not quantitative research.

In the LUMC there is a risk classification system for medical devices (§ 4.4.2). It is developed internally with help of an external party. The current risk analysis comes from 2004 and classifies devices in three categories: high, medium and low risk. This classification system aims to improve the awareness of the users of the risks with a device. Furthermore it is used as a factor for of maintenance routines. The classification system is not flawless for three reasons. First, it is not updated since 2004, making it vulnerable for the evolutions and revolutions in the technological and clinical development of a medical device. So currently it is not guaranteed that a device is classified in the risk class it should be placed in. Second, the risk classification is not orientated at the user context, while the context in which a device is used does effect how the device is operated. And that is of influence of the safety of personnel and patients. Third, the classification system can give another outcome when another staff member fills in the same classification scheme. It is thus sensitive for personal judgements.

There is currently a list in FLITS that contains medical devices that can be ordered from a supplier that already delivers the medical device to the LUMC (§ 4.4.1). The list is aimed at improving the
standardization of goods in the LUMC. Users ordering a similar device will be suggested to purchase the standard item. The purchase department, who is also active and responsible in improving standardization, maintains the list. The items on the standard list are not assessed with a risk analysis at this moment. Furthermore the standard list only contains an entrance, not an exit. Products are not removed from the list, as is found in the discussion with the operational responsible employee of FLITS.

During the interviews there were indications that the clinical physicist is involved in the procurements with the task to estimate risks. It was only indicative; there was no clear indication that the users saw the clinical physicist as the person to go to for risk classification.

§ 5.3 Summary of comparison of sub-question 2 and 3

The two relevant performance indicators of the NVKF are quantitative indicators, which cannot be answered in this research, as this is a qualitative research. The NVKF performance indicators have a direct relation with the two criteria of NIAZ that are relevant for this research. The NIAZ requires regulation not only to be present, but in use as well (table 2.2). This comparison searched for regulation that was actively used, not if it was present. The two relevant NIAZ criteria are:

<table>
<thead>
<tr>
<th>411.01</th>
<th>The institute has a regulation for the procurement of all the kinds of goods that are used within the institute. This regulation specifies the following points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>411.01a</td>
<td>The way that experienced employees are involved in the selection process, if the procurement is for goods or devices used in the healthcare processes</td>
</tr>
<tr>
<td>411.01b</td>
<td>The way in which the selection and judgement of the suppliers of goods is carried out</td>
</tr>
<tr>
<td>421.01</td>
<td>The institute has regulation for the process of risk analysis in the beginning of a procurement of (medical) devices, meant to guarantee the quality during use. [part of NTA 8009:2007]</td>
</tr>
</tbody>
</table>

For criterion 411.01a it was found that there is currently only regulation in use for the involvement of the purchase department and the radiation hygiene expert for the selection process. There is currently no regulation in use that specifies the way to involve other facilitating departments (infra, clinical technology, sterility, ICT) in the selection process. Additionally, there is no regulation in use that specifies the way the user(s) should be involved.

For criterion 411.01b it was found that for procurements below € 250k currently there is no regulation in use that determines how the procurement leader should select and judge a supplier. For European tenders (investments above € 250k) there is regulation in use that prescribes how a European tender should be carried out. One weakness is that the selection algorithm is not tested thoroughly. This prevents a reflection if the algorithm and the weights represent the users preferences.

For criterion 421.01 it was found that there is a classification system present and in use that pre estimates the risk a device poses for patients. The classification system was developed in 2004, and is now outdated. There is also a standard list of items in the payment system FLITS, that provides users with an incentive to by an item that is standard in the LUMC. The standard list is not developed with risk for patients or personnel in mind.

The classification system and the standard list are items that do not provide a risk analysis for each procurement. The NIAZ requires there to be a risk analysis done for each procurement. There were some indications during the interviews that indeed the clinical physicist is active in risk analyses in
procurements. It was however not a convincing finding that clinical physicists are indeed involved for every procurement to perform a risk analysis.

§ 5.4 Answer to sub-question 4

From the previous paragraph a several problems with the current procurement process are found. As this research project is limited by time, only for one of the problems an advice is developed. From the previous paragraph it is found that the procurement process does not fully comply with the relevant quality criteria of NIAZ. It is found that for most procurements:

1. No regulation is in use that describes the way experts should be involved [411.01a]
2. No regulation is in use that describes how a supplier should be judged and selected [411.01b]
3. No regulation is in use that describes what a risk analysis at the beginning of a procurement should consist of in order to guarantee the quality during use [421.01]

From these three points a choice has to be made for what should be improved. From the viewpoint of the LUMC all these points should be improved, as that is required to truly comply with the NIAZ criteria. As is stated before, only one problem will be addressed in the rest of the research. The choice is made to focus on problem 1. There is a logical argument for this choice:

Solving problem 1 provides a solution the way expert should be involved in the procurement process. This is a precondition for problem 2 and 3 to be solved as well. It is not possible to make a good selection without having experts in the procurement team (problem 2). It is not possible to do a risk analysis without the experts in the procurement team (problem 3). The logical argument is that for a procurement process first problem 1 needs to be solved in order to make it possible to solve problems 2 and 3. This subparagraph is concluded by answering:

Sub-question 4: What should be improved in the current way procurements are carried out?

The answer is that the current formation of a procurement team should be improved, with a focus on the way experts are involvement in the procurement.

The definition are explained below:

‘The way’ is a definition that originates from the NIAZ criteria 411.01. NIAZ does not define what the way means as it believes that hospitals should be free to organise ‘ways’ by themselves. NIAZ will check and certify that it is organized, not how it is organized (NIAZ, 2009).

‘Experts’ (NIAZ refers to experienced employees) are assumed in § 5.1 to be the staff of the facilitating departments and the users of medical devices. Their expertise is bounded by the specialty they work on. They are only knowledgeable on what they work on. In addition the clinical physicist is also seen as an expert, on a very specific field. They all have a background in applied physics, and work on fields were physics and healthcare come together.

A procurement team is defined here as the personnel that is involved in the procurement with the purpose to contribute in the content of the formation of requirements, selection of suppliers and user tests of the procurement, or any other activity that is needed to complete a specific procurement.
CHAPTER 6. DEFINITION OF RESEARCH FOR THE ADVICE

In Chapter 5 it is found that the formation of a procurement team should be improved, with a focus on the way experts are involved in the procurement. The rest of this report will build up an advice on how that could be improved. This chapter defines what is researched and how it is researched.

First requirements on the advice are formulated in § 6.1. In § 6.2 the sub-questions are defined that are required to be answered for the advice. § 6.3 presents the scope of the advice, so to make clear what the form of the end result will be like. § 6.4 presents the approach to answer the sub-questions.

§ 6.1 Requirements for an advice

This chapter defines the sub-questions that are necessary to answer before the main research question can be answered. Before the sub-questions are stated, the requirements on the advice are explained to provide context to the reader why a sub-question is important to be asked.

Requirements from the organisation

From the interviews a few requirements are identified that will have to be met for the advice to be acceptable and functional for the LUMC.

First of all it is seen that the medical staff, the users of medical devices, do not want to be overloaded with bureaucracy (§ 4.7.2). In their opinion they are well capable of procuring their own specific medical devices and fear that a solution for them creates a time consuming process, which is useless and can be better spent on the core process. They are supported by the executive board of the LUMC, who is of opinion that the solution should be dynamic in nature to prevent the procurements from utilizing too many resources. This requirement limits the use of resources of the advice. When the advice is implemented as a procedure, the advice may not lead to an inappropriate use of resources. This requirement refers to the problem definition, which stated “(…) The improvement must be acceptable for the executive core, as they are crucial for the successful use of the improvements”. Hence, this requirement says something about being acceptable, although being acceptable also depends on how the advice is implemented, something which is not under study here.

The outcome of the advice should improve the safety of patients and personnel. Improving safety is the leading goal throughout this report, as is stated in § 1.1.2 and is elaborated throughout this report.

Requirements from external regulation

There are three sources of external requirements relevant for this research from, NIAZ, the NTA 8009:2007 and the Quality Law for Healthcare Providers (Kwaliteitswet voor Zorginstellingen). The requirements all come from a concept that is developed for a quality management system. These are:

- The procedures should be part of a quality management system, which is part of a continuous cycle of implementation, use, measuring and improving, of this the advice
- The responsibilities and tasks with the procedures’ are clear to all and are in use by all

‘Procedures’ is used here to indicate the implemented advice. These demands influence a far wider area than is under research here. This research is not concerned with the implementation, measurement or improvement of the advice. But it is important to keep in mind that the advice needs to be implemented, used, measured and improved.
The requirement of clear responsibilities and tasks are in this research not the main concern. It is the responsibility of the hospital to appoint and create the proper structure that is required to use the advice in the real world. This research will provide an advice.

Summarized, the three requirements coming from the organisation and from external regulation are:

1. The use and of the advice may not lead to an inappropriate use of resources
2. The advice must contribute to the safety of both patients and personnel
3. It must be possible for the advice to be implemented in a guaranteed quality management system

§ 6.2 Definition of sub-questions for the advice

In Chapter 1, sub-questions 1 to 4 were raised, with the reservation that the sub-questions that focused on the advice could only be asked after it is known what should be improved. That is answered in parts 1 and 2. So now the sub-questions are asked for the advice. The main research question is:

_How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?_

The main research question and the requirements form the input to formulate the last sub-questions. Before answering the main research question, it needs to be known what the possibilities are to improve the quality of a procurement. This is a general question that also includes the way experts are involved in the process. This general question is asked deliberately. There are three main problems with the current procurement process (§ 5.3) and here only one problem will be solved. An advice that solves one problem also will influence the other problems. It is practical for the problem owner if the advice that is formed here also provides a basis to solve the other problems. This leads to the following sub-question:

_Sub-question 5: What are possibilities to improve the quality of a procurement?_

This research aims to increase the safety during use of medical devices, by improving the quality of a procurement. The focus became on the way experts are involved in the procurement. Involving experts requires an indicator to involve them and as this research is about the quality of the procurement (and the resulting safety during use), this raises the last sub-question:

_Sub-question 6: What factors are indicative for the required quality of procurements?_

With sub-questions 5 and 6 is it possible to answer the main research question, presented in § 1.6.2

§ 6.3 Scope of the advice

The advice must provide the procurement leader with a possibility to base its decision for the formation of a procurement team. This requires the advised solution to be usable, understandable and trustworthy. Also the form of the advice is discussed here.
Form and usability of the advice

The NIAZ Quality Norm Healthcare Institute (Kwaliteitsnorm Zorginstelling) (2009) does not provide clarity of what it sees as ‘the way’, as it is more important to achieve the end result of guaranteed quality. It is intentionally open to interpretation what ‘the way’ is, so that hospitals are free to use any way they prefer. In this research ‘the way’ will be defined as being a framework. This does not make the definition less abstract than it was, but it is a more common and formal definition.

Because the emphasis is not on what framework is used, but on what the framework makes possible, the emphasis in the advice should not be on the type of framework, but what the framework should be capable of achieving. On a high level this is guaranteeing quality of care. On an operational level it means guaranteeing that the required experts are in the procurement team when they are needed.

As the framework itself is of less important, it needs to be determined what this framework will provide to the problem owner. The framework that is developed in this report will provide the problem owner with a possibility to improve the way experts are involved in the procurement process. It is specifically not a solution, but only an opportunity. In the end there are a lot of operational parameters that are not known at this moment by the author and which are only known by the experts in the hospital. The framework that is developed at the end of this research is not ready to be implemented. First it needs to be completed so that it includes operational parameters. Only then can this framework be seen as a solution.

The advice will try to provide a framework that is also (partly) useful for solving the other two problems raised in § 5.3, although that is not the main aim.

Understanding the advice

As defined in the previous sub-paragraph, this framework will provide an opportunity to make a solution; it is not a complete solution, as operational parameters first need to be used to complete the framework. This framework must therefore be understandable for the people who are going to be make the advice into a complete solution. But at this moment that is not known, so this part of the scope cannot be determined.

Trust in the advice

There are three possibilities to gain trust in the proposed solution.

The first possibility is to verify and validate that the proposed solution works as intentioned. As this is not a mathematical problem, nor is it related to a similar system, verification and validation will be effortless and will not increase ones trust in the advice.

The second possibility to increase trust is to ask experts to judge the proposed solution. This requires the solution to be explained to experts in this problem area, who then judge the system on its capabilities to solve the problem.

The last possibility is to use the framework in reality, be it on a small scale or for the whole hospital at once. It is possible to introduce this framework on a large scale at once as long as the outcome of the framework is not binding, so to prevent unforeseen and unwanted side effects. This makes it possible to receive a lot of feedback in a short time from the various types of procurements that are present in the LUMC that can be used to improve the framework.

This research will not use one of the three frameworks for gaining trust in the advice. Verification and validation will prove to contribute little to the trust of the system. Expert judgements require a vast amount of time, which is not available for this research. Using the framework in reality in order to gain trust in the
solution is a possibility that can only be carried by the LUMC, but only after the advice is finalized with the operational parameters by the hospital.

**Summary of the scope of the advice**

The advice that is given with the answer to the main research question will provide a framework that can be used in a procedure to select the way the experts should be involved. The advice is a framework that requires refinements by the hospital personnel, as operational parameters are not known at this moment in this research. As the advice is not yet a solution and certainly not a tailor made procedure, it is not possible to test this framework so to gain trust in it.

### § 6.4 Approach to answer the sub-questions and the main research question

Here per sub-question and for the main research question it is described how the answer is given. All three questions are for the largest part answered by a creative design process, as literature on a topic that combines procurements, risks and hospitals are non-existent, as described in § 1.3.

#### § 6.4.1 Approach to answer sub-question 5

First a definition based upon the interviews and the main research problem is formulated for the term ‘quality’. Then a review of literature that is present on procurements aims to provide ideas to improve procurements. The literature comes from the field of supply chain management, of which procurements are a part. This field of studies is chosen, as it was impossible to find valuable literature on the field of procurements related to hospitals or healthcare.

Besides literature, the interviews provided a source of possible improvements. The interviewees were asked what they think is a good possibility to improve the current process. Besides the input for the interviewees, the authors own creativity is used to think of possibilities.

#### § 6.4.2 Approach to answer sub-question 6

This question strives to find the factors that stand for the quality of the procurement. First a definition based upon the interviews and the main research problem is formulated for the term ‘quality’. This provides input in the design of a causal diagram that presents the relations within the hospital that influence quality during use. With a selection procedure that is aimed to select the factors that can be influenced during a procurement, the factors are selected that are indicative for the quality.

#### § 6.4.3 Approach to answer the main research question

The indicative factors together with a to-be designed of framework factors are used to answer the main research question. The factors are partly operationalized to be indicative for the quality. The framework provides a choice in which format the experts should work together. Together the framework and the indicative factors present a complete basis for the hospital to start implementing procedures to improve procurement, so to increase the safety during use of medical devices.
In this chapter, the possibilities on how to improve the procurement quality are reviewed. It presents measures that have a potential to improve the quality.

To make it possible to improve the quality of the procurement, it needs to be defined how quality for procurements is defined. This is defined in § 7.1. In § 7.2 it is explored in the literature what is present as means to improve quality as defined in § 7.1. § 7.3 presents the approach to find and discover these means. In § 7.4 the means are presented and discussed on by one. This provides possibilities to improve the quality of a procurement. This will answer:

**Sub-question 5: What are possibilities to improve the quality of a procurement?**

The answer to sub-question 5 will be used as a basis to improve the current procurement process. The answer to sub-question 5 provides much more ideas to improve procurements than is the focus of this research. This research will only focus on how experts are involved. The ideas provide a start for the problem owner to improve the procurement process further.

### § 7.1 Defining procurement quality

In general, quality can be defined as the measure in which goals are achieved. Translated to this research problem, it means that the procurement quality is high if a procurement is described that uses a low number of resources while it does make it possible to guarantee the safety of patients and personnel as much as is possible with a procurement. Quality then becomes measured by two factors, of costs of a procurement (this also includes the time spend on it) and the number of preventable adverse events with devices. The indicators for that last factor are already researched in the previous chapter, but it is not researched what measures there are to mitigate preventable adverse events during use in a procurement. That is researched in this chapter.

### § 7.2 Review of literature

In order to determine if literature is relevant for this research, two factors are determinant. First it will be reviewed what the goal and possibilities to improve procurement are. Second, it will be reviewed on what basis indicators are used to select the appropriate management and governance level of the procurement. For this research project that will be based on the potential risk. Two books are chosen to be reviewed, which will be referenced to in the coming paragraphs.

#### § 7.2.1 Goals for a procurement process and possibilities to improve procurements

The first book, by Monczka, Trent, and Handfield (2005) and called purchasing and supply chain management, defines the goal for procurements to minimize costs. There are multiple strategies defined to reduce the costs, which all focus on reducing the various transaction costs, while maintaining enough control over the resources. The procurement of medical devices can also be viewed from the side of transaction costs. The complication is that the transaction costs in the procurement of medical are hard to estimate for risks.
The second book is from Bowersox, Closs, & Cooper (2002) and sees the goal of procurements as a vital part of keeping the core processes running, by providing the right goods and materials. The goals of procurements are to ensure a continuous flow of supplies, inventory minimization, quality improvement, supplier development, and lowest total costs of ownership. Particularly the quality improvement and the lowest total cost of ownership are interesting subjects for this research project. Again, the total cost of ownership is hard to estimate for the whole life cycle of a device, let alone compare it between devices. The quality improvement goal is completely focused on industry production processes that take in account costs of decreased production costs and decreased warranty claims as an advantage of the focus on quality. This is not useful for this research subject.

§ 7.2.2 Governance and strategies

In Monczka et al. (2005) the governance level of a procurement is determined by the size of the investment for the procurement. The trade-off should be made between the potential costs that can be decreased by appointing a project team, and the costs of the project team. If the cost reduction is larger than the costs of a procurement team, it is logical to appoint a project team. The higher the total costs of the investment are, the higher in rank the leader of the procurement should be.

Such a system that requires a higher ranked procurement leader based on costs is somewhat present in the LUMC. Above a budget of € 50k it is obligated to involve the purchase department. Above € 250k it is obligated to inform the executive board about decisions. There is not a system that makes the trade off between potential costs reduction and the erection of a project team. Monczka et al. wrote this book with an industrial company in mind. For them cost reduction is a way of making more profit. For hospitals in the Netherlands cost reduction became an aim only recently, and procurements of devices are a small financial post.

A possibility to make this previous viewpoint interesting is to interchange total procurement costs with risks. Then the governance level is determined by the amount of risk the procurement poses for the patients and personnel. This is a useful analogy of the industry oriented supply chain theory for the service sector.

Bowersox et al. (2002) aim to use a proper strategy for the different kinds of procurements. The difference between procurements is based on the strategic importance the resource (or device) has for the organisation. Three strategies are defined, which all aim at reducing costs. The three strategies are volume consolidation (buying all from one supplier), supplier operational management (integrate administration and processes), and value management (integrating design of processes and products). The more crucial a procured product for an organisation is, the more integrated with the supplier the buyer should become. For academic hospitals these strategies make it possible to increase safety. As a conceptual example of value management, if the LUMC would be involved in the research and development of a diagnostic device, this gives them possibilities to alter the design to their needs. This creates possibilities to increase safety for patients. This method cannot be used for all the items in the LUMC, only the highly advanced ones who are interesting for research. Developing research disciplines takes many years. Supplier operational management could become interesting for the supply of common disposable products, as this would reduce the costs of inventory management for the LUMC. But it does require a large investment to acquire a digital real time inventory system, something that may not be that profitable at the end. Volume consolidation is a strategy that is currently used by the LUMC, by striving for standard items. This has direct purchase and maintenance advantages.
Although these strategies all have their advantages and can be applied to procurements in the LUMC, these are not applied strategies with the aim of reducing risks.

§ 7.2.3 Result of literature review

The literature on the topic of healthcare procurements with a focus on safety is not present. Why this literature is not present is not known for a fact, but it is found that until recently the applied environment of healthcare (hospitals themselves, but also their regulators) did not have attention for procurements of devices. Healthcare is a service industry, and service industries tend to focus on the people that are hired, instead of the capital in house, for the practical reason that people consume the largest part of the budget. This is also true for the academic hospital (60 % for the LUMC). That the healthcare sector now starts focussing on the procurement of medical devices is only for patient and personnel safety. Devices now pose a threat to the core services and the personnel, so it now becomes a topic of concern and research.

Therefore another field of research is chosen which is well developed in controlling its processes, including procurements. The literature comes from the field of supply chain management. It was found that this field has one focus: costs. All that is to be determined about governance and control of a procurement is written from the viewpoint of total cost of ownership. This research has a focus on risks. As a cause, the literature of supply chain management is not useful for this research. All measures are focused on lowering costs, not reducing risks.

§ 7.3 Design approach of possible improvements of procurement quality

In the previous paragraph it is indicated that the literature from supply chain management is not applicable to procurements in hospitals for the purpose of reducing risks. Neither is concrete literature available on procurements in hospitals, aimed at reducing risks. This paragraph will therefore present applicable and concrete measures that can be taken to improve the procurement quality, so to reduce the risks for patients and personnel during the use of a device.

§ 7.3.1 Development of an end-means diagram

In order to display the measures that are available to improve the quality of a procurement, an end-means diagram is used. In this type of diagram the end goal is supported by all kinds of possible means, also called measures. A mean can be directly supportive to the end goal, or it can support other means. It creates a possibility to introduce a wide variety of possible means. The inspiration for all these measures come from the actor interviews literature were applicable, and from a creative process.

§ 7.3.2 Presentation form of the end-means diagram

As with the presentation of the causal diagram, the means are presented in groups to make the presentation more structured for the reader. The means can be grouped by multiple viewpoints. In chapter 5 the presentation of procurements was done with a conceptual diagram that divides the procurement in chronological steps. It is also possible to divide the procurement along the different aspects that are present in a procurement, such as governance, policy, process and information. That last approach is not chosen as it hard to classify measures in just one group. Here it is chosen to classify chronologically. As means can support other means, it can be illustrated how they support another.
§ 7.4 Presentation of the end-means diagram

The presentation of means is done along the chronological definition that was presented in figure 4.1. Every step has its own colour. The steps of chapter 4 are; formation of a procurement team (black), specification of requirements (green), selection of supplier (blue), and acceptance and payment (purple). As payment is not contributing in any way to the quality of a procurement (from the view of the hospital at least), this will not be mentioned here again. The whole end-means diagram is presented in figure 7.1 at the end of this chapter (page 79). In that diagram the end is the red block quality of procurement. The procurement examples stated here can be found in Appendix F.

§ 7.4.1 Selection of procurement team

The selection of a procurement team is displayed with black blocks. The explanation is top-down.

- **Make a planning**: a planning provides an overview what needs to be done and when it is done. Additionally a clear overview of who performs what part is a crucial addition for a procurement team. In the case of the procurement of syringe pumps a great delay arose and the subgroups were not aware what their purpose was, nor were their work was used for.

- **Specify appropriate supervision**: appropriate supervision means that the right supervisors for the procurement team are chosen. For example, a hospital wide procurement deserves the supervision of the executive board, while a procurement of two departments in one or two divisions can be supervised by the involved division boards. A small procurement for one department may only require the supervision of the department financial responsible person, while a more expensive procurement requires supervision of the division board. Here the investment class plays a role, but what this research aims for, is that also risk can be taken into account to appoint proper supervision.

- **Assign knowledgeable procurement leader**: as people get more experienced in a task, they become better in it, be it in time, quality or quantity. This is known as a learning curve. Assigning a knowledgeable procurement leader in a procurement will thus improve the quality of the procurement. The quality is improved as such a procurement leader has a better understanding who to involve, how to plan, which supervision is required, what weighting distribution is proper and if a risk analysis is necessary.

- **Involve staff with technological knowledge**: in order to procure a medical device, it needs to be known what the technical requirements are. One can think of requirements for the room, the utilities, ICT, but also requirements of importance for maintenance and proper device operations (especially relevant for diagnostic devices). Two procurements, both for telemetric devices, illustrate that the departments that were procuring did not possess enough knowledge about ICT to successfully procure the devices. This mean supports risk analysis, prioritization of requirements and the development of focus groups.

- **Involve staff with user knowledge**: in order to procure a user friendly medical device, it needs to be known what the requirements of the user are, so user knowledge needs to be brought in the procurement. As obvious as it seems, the user requirements for the procurement of beds were not specified clear enough for safety consideration of the user, or the patient, which has led to unsafe beds for both patient and personnel. This mean support is many other means, but the most important ones are the performance of a risk analysis, prioritization of requirements, specification of requirements, specifying users tests and developing focus groups.
§ 7.4.2 Specification of requirements

This part contains the largest number of means. That is logical, as the specification is a phase that is under full control of the procurement leader. This part is described top-down.

- Improve specification of requirements: this is a general means that is explicated by its supportive means, which are described below.
  - Increase market knowledge: Increasing market knowledge is important. It provides the procurement team with the required knowledge of what is actually possible to procure and what specific prices are. That could have an influence on the requirements that are formulated. The supportive means are:
    - Make producer visits: visiting producers increases the insight of what is possible on the market. Especially when it is a genuine new device, or a high-tech device, this can increase the awareness of what is and what is not possible.
    - Make hospital visits: visiting other hospitals that are providing the same functions with new devices provides a possibility to talk about experiences with the devices, something that the producer will not tell honestly. And it presents a possibility to exchange experiences with procurements as well.
    - Search for products: besides making visits to producers or hospitals, a market orientation will start with a search for products on the web, by asking brochures and phoning producers.

- Specify user test: during the specification of requirements, also a user test could be part of the specifications that are judged. This provides the possibility to cope with topics that are hard to specify, such as the interaction between user and device. User tests make it possible to measure that factor, which can be used as a requirement. In the procurement of suture the user test was not defined applied enough, which resulted in a process that mixed up training and testing. Then the test results become biased by the training. Many pitfalls exist for user test, but these are out of the scope of this research. The message is that it should be well defined what and how it is performed.

- Optimize selection algorithm: When the program of requirements is completed, a selection algorithm can be formulated. For European tenders this is obliged, not for other procurements. Still it can be performed for all procurements. The advantage of formulating this in the specification phase is that the procurement team is unbiased towards suppliers and their offers, so it provides an opportunity to perform an objective selection process.

- Improve program of requirements: the program of requirements is a document that contains all the requirements and wishes, preferably in a prioritized order. The improvements are achieved with the five supportive means, which are discussed below.
  - Distinguish between wishes and requirements: by making an explicit difference between what is a requirement and what is a wish, it will be easier to develop an algorithm, assign weights and to improve the overall quality of the program of requirements.
  - Prioritize requirements: when a priority is made, it becomes clear what the procurer values the most. It forces the procurer to think about its specification and the choice between wishes and requirements. This mean is supported by the involvement of technical and user knowledgeable staff, as they can know what the importance is of requirements.
  - Specify requirements: The bases for the requirement specification are the requirements themselves. These are formulated on basis of the function that needs to be performed, the
relation the device has with other devices and with users and on additional requirements, such as sterility, maintenance or radiation requirements. It is important to keep in mind that requirements exist in two types; the requirements that the device must possess, and requirements the device must not possess. The two types are not opposites.

- **Perform risk assessment**: a risk assessment about the medical device itself and the relation to the user (environment) provides more insight into requirements that must be formulated to guarantee safety. Furthermore it can be discovered with a risk assessment that with the introduction of a new device certain work routines need to be changed, or that policies are in conflict with the operation of a device. These are important findings.

- **Assign weights to requirements**: the prioritization of requirements can be expressed in weights that are given to each requirement. The purpose of the weights is to be used in the selection algorithm. So testing if the distribution of weights actually does represent the preferences of what needs to be procured is necessary to avoid a dissatisfying outcome of the selection phase.

### § 7.4.3 Selection of supplier

The selection of suppliers contains relatively little means, as most work is already prepared in the specification of requirements. This paragraph is described top-down.

- **Optimize selection of suppliers**: optimization can be done in many different ways. The emphasis of the selection in this end-means diagram is placed on the specification of requirement phase. With all the means described above a very good comparison of devices can be made. For smaller procurements, many of the supportive means may be over the top. Another effective way of optimizing the selection is by making a fair comparison possible. This can be achieved by listing all the outcomes of the requirements next to another. This provides the possibility to compare offers of producers. Next to the already discussed means, two other means support this mean:

  - **Perform user test**: a user test can already be specified in the previous stage. Performing a user test requires a good organisation. With a user test it is possible to judge devices and then chose the one that is most convenient for the user. Convenience can be measured on criteria as the interface, the treatment time and quality and testing and cleaning possibilities. The environment can be diverse, from a lab environment, up to the complete implementation in the work processes. A thorough test of a couple of potential medical devices can be a very effective method to keep not well-designed medical devices out of the hospital.

  - **Select experienced producers**: a good way to improve safety is to select only those suppliers that are known to produce a certain device type for a long period without known problems. This rules out the mistakes that beginning companies make.

### § 7.4.4 Acceptance

The acceptance contains relatively little means, as it is a phase with the least amount of actions. This paragraph is described top-down.

- **Improve acceptance**: this is a generalized mean, which is made more operational with these means:

  - **Perform stress tests**: by stress testing a device it becomes clearer when a device malfunctions. This should not only consider stress testing the requirements as in the manual, but also testing
it with the eye of an untrained user. This reveals the required amount of training that is required and the weak points in the design of the device.

- **Test device along requirements**: when a device is selected, it must be tested if all the claims on requirements of the supplier are actually present (or specifically not present) and working. This is a basis of an acceptance test. As there are requirements formalized from the technical and the user perspective, also both perspectives should be tested. Currently the usual practice is that clinical technology only tests the technical requirements of active medical devices, before releasing it. The user side test is not a secured process for active medical devices and there is no process of acception present for the non-active medical devices.

- **Analyse manual(s)**: This is a point that comes straight from a comment from the IGZ in its report of 2005, and from experiences within the hospital. The IGZ has determined that manuals are often missing, or in English. This is not according to the law. The experience in the hospital was that a summarized version of a original manual contained a significantly different operational procedure, which could have led to a preventable adverse event. Analysing manuals on such mistakes would increase the safety of the patients.

### § 7.5 Answer to sub-question 5

This chapter provided the answer to:

*Research sub-question 5: What are possibilities to improve the quality of a procurement?*

The quality of a procurement is defined as the measure in which the goal of improving safety is supported as far as possible for the procurement phase. For the answer of this research question a literature review was done. Procurements in general are only recently a topic of study. More specific, no research is available how procurements can improve the safety of patients, other than was already presented in previous chapters.

With help of this literature, the inspiration of the interviews, and ones own creativity, an end-means diagram is presented. The end means diagram (figure 7.1) presents how each mean, or measure, contributes to the improvement of the quality of the procurement. The end-means diagram also indicates the relations that exist between means.

The means in the diagram are coloured to indicate in which phase they are ‘activated’. Of course a mean can be used in a later phase, but not earlier. The colours indicate the following:

- **Black** formation of a procurement team
- **Green** specification of requirements
- **Blue** selection of suppliers
- **Purple** acceptance of device
- **Red** the end goal that is supported by the means
Part 3

Design of an advice

Figure 7.1
End means diagram for improving procurement quality

Increasing procurement quality

Improve acceptance

Improve specification of requirements

Optimise selection of suppliers

Perform stress tests

Test device according to requirements

Analyze manuals

Specify appropriate supervision

Make a planning

Specify requirements

Perform risk assessment

Prioritize requirements

Distinguish between wishes and requirements

Select experienced producers

Improve program of requirements

Optimise selection algorithm

Perform user tests

Specify user tests

Perform user tests

Increase market knowledge

Make producer visits

Make hospital visits

Search for products

Develop focused subgroups

Assign weights to requirements

Assign knowledgeable procurement leader

Involve staff with user knowledge

Involve staff with technol. knowledge

Assign weights to requirements
CHAPTER 8. FACTORS INFLUENCING PROCUREMENT REQUIREMENTS

This chapter will investigate what factors are indicative for requirements on the procurement of a medical device. This is done by providing a causal diagram, out of which the indicative factors are selected, so to provide the answer to:

Sub-question 6: What factors are indicative for the required quality of procurements?

With the answer to sub-question 6 it is aimed to make it possible in Chapter 9 to connect it with factors influencing the procurement quality. With that connection it is possible to answer the main research question.

§ 8.1 will describe the approach to construct a causal diagram. In § 8.2 the causal diagram is constructed. § 8.3 then will identify factors in the causal diagram that are indicative for the required procurement quality. § 8.4 presents the answer to sub-question 6.

§ 8.1 Approach to construct a causal diagram

In order to select factors that can be indicative for the required procurement quality, one can simply seek for measurable factors that have to do with safety. This would be an unstructured approach that will lead to arbitrary decisions on which measurable factors to select. Therefore here a more structured approach is chosen. The construction of a causal diagram provides the possibility to argument why which factor is required and what the relation between factors is. The causal diagram also provides a possibility to make a selection between factors based on criteria, so to select only indicative factors.

The construction of this causal diagram is done with use of theories, findings from the interviews and assumptions. The boundaries for the causal diagram are deducted from the problem definition and the research boundaries that were presented in Chapter 1. They are listed here:

1. This causal diagram aims to present all factors that are of influence on the safety of patients, in relation to factors of the use and introduction of devices that can be determined or influenced during procurements. This excludes incidents that are only caused by direct failure of humans or organisations.

2. It aims to clarify the interaction of the procurement phase on the phases of introduction and use. This is explicated in Chapter 9. The causal diagram is not intended to clarify the interaction of the introduction and use if that is not relevant for the procurement phase.

A causal diagram has a large amount of interrelated factors. The presentation of this causal diagram is divided up into parts, in order to make it possible for the reader to understand the diagram and not be overwhelmed when it was presented at once. The parts of the causal diagram are based upon the phases in the procurement, which are use and introduction, the device characteristics and the main performance criteria for a hospital. Other parts are main performance indicators and causes of incidents. Each part is described and build into a diagram in the coming paragraph.

In 0 the explicit causal diagram (figure G.4) and a factor list (table G.1) are given. A factor list gives the unit of each factor. It is strived to make the unit in which a factor is measures as objective as possible, so to avoid an influence on the measured factor by the person measuring. The causal diagram displays the
positive (+) or negative causal (-) relations between factors. The construction of the factors is discussed in the coming paragraphs. Each part is ended with an addition to a summarizing diagram.

§ 8.2 Construction of the causal diagram

The construction of the causal diagram is divided in the parts main performance indicators, causes of incidents, device properties, usage characteristics and introduction, which are described below.

§ 8.2.1 Main performance indicators for hospital

This paragraph contains two types of indicators. The first one is about device related incidents. The second indicator is related to costs.

Device related incidents

From the strategic plan discussed in Chapter 1 it is learned that the LUMC values quality above all for their core businesses of education, providing care and research. Quality is not a tangible factor for the society. It is hard for society to measure it, or to compare it with other hospitals. There is the annual publication of publisher Elsevier, of what the specialists themselves see as the best hospital. And there is the annual presentation of the Prestatieindicatoren (performance indicators). But it remains hard for the society to judge and compare hospitals. The one thing that became important for society, is the image of hospitals. But image became a harsh indicator, which is prone to incidents that become published in the media. In this causal diagram, the number of preventable adverse events, and especially the number of preventable deaths have a negative influence on the image of hospitals. Here it is assumed that there is a positive effect from preventable adverse events on preventable deaths. In all publications about patient incidents this is assumed, or proven. This research will also assume that there is a relation, in accordance with reports mentioned in Chapter 1 of Willems (2004), the Institute of Medicine (2000) and Wagner et al (2007).

Most people can remember recent incidents in hospitals in which patients were harmed or even killed in hospitals. The one thing that they do not perceive is the amount of near misses. Near misses can be a valuable source of information for the hospital for the improvement of their process. This research is not focused on learning from incidents, but on how a procurement can contribute to safety. Near misses, and the whole loop of learning from incidents is for that reason not taken up into the causal diagram.

The last factor – which is actually not a main indicator, but is part of ‘device related incidents’ – is the costs per preventable adverse event. This cost indicator is an average that can be used to calculate the loss of money by the amount of incidents that occur in the hospital.

All these factors are summarized in figure 8.1.
Costs

Another performance indicator that is of importance for the hospital, are the costs. Money is a scarce resource in the healthcare sector. As explained in chapter 1 and found in § 4.7.2, specialists do not want to use processes that evade costs of their primary processes. By combining all costs into one picture, it becomes possible to indicate advantages and disadvantages of shifting resources from one factor to another. All costs that are listed in figure 8.2 include the costs of personnel and material. As most items are self explanatory, only the ambiguous ones are explained here.

The costs for incidents can be calculated in many different ways. For example, the IMTA\textsuperscript{13} also includes the costs of secondary effects, like loss of work capacity, and the costs of effort to compensate that loss. Here only the costs for the hospital are listed, which can depend on the extra nursing and material that needs to be provided and is not paid by the insurer, and possible claims of the patient. Purchase stands for the costs for purchasing a device. Introduction stands for the costs that are needed to train personnel, but also the costs that are needed to make the device operational. Costs for procurements are the costs that are specifically made for the procurement of a device.

The figure 8.2 summarizes all the costs.

\textbf{figure 8.2} factors for costs

§ 8.2.2 Causes of incidents

There is a lot of data available on patient safety incidents. This data is categorized using models, of which two are presented here. The first method is called PRISMA, and is developed by in the Eindhoven University of Technology for the chemical industry and adapted for the health ‘industry’. Another method is IPSEC, from the WHO, which aims to be unbiased in any way towards cultures and healthcare systems around the world. It is specifically developed for the healthcare sector. This analysis method is not used, as the aimed at identifying problems of medical procedures in relation with humans and the system of healthcare provision. The categories are listed very specific towards human behaviour and system behaviour related to the operational processes.

PRISMA stands for Prevention and Recovery Information System for Monitoring and Analysis, and is a retrospective analysis method. Here only the medical version of PRISMA is discussed, as described in PRISMA-medical (Schaaf & Habraken, 2005). The method is grounded in the model of Rasmussen who distinct human behaviour in Skill-based, Rule-based and Knowledge-based, of which each level requires more conscious attention to perform. Next to that PRISMA is based upon tests with incidents coming from the healthcare sector (Vuuren, Shea, & Schaaf, 1997).

\textsuperscript{13} Institute of Medical Technology Assessment, part of Erasmus University
PRISMA aims to provide healthcare institutions with a method to learn from incidents and change their processes. This is an applied aim, which is reflected in the method with three-steps guide to carry out PRISMA. The steps are:

1. Incident description; consisting out of causes, effects, countermeasures
2. Cause classification; consisting out of the classes technical, organisational, human, patient related and unclassifiable
3. Problem solving; presents multiple possibilities to solve the problem, related to the cause

For this research especially step two is of interest as it describes the causes of device incidents, which is exactly what is needed to continue to the build up of the causal diagram. In the PRISMA method four main cause sources are introduced, each with more specific causes:

1. Technical
   a. External; errors caused by factors out of reach of the problem owner
   b. Design; errors caused by design (material, interface, aiding material, software, shape, label)
   c. Construction; errors caused by construction which deviated from the design
   d. Material; errors caused by material defects not listed under 1b or 1c
2. Organisational
   a. External; error on an organisational level outside the control span or responsibility of the problem owner
   b. Knowledge transfer; error caused by insufficient measures that could guarantee the proper transfer of domain and situation information and knowledge to all new or inexperienced employees
   c. Protocols; errors caused by the quality and availability of protocols (too complicated, inaccurate, not complete, unrealistic, absent, not well presented)
   d. Management priorities; decisions of internal management in which safety is given a lower priority as an effect of conflicting interests or goals. It is a conflict between production demands and safety
   e. Culture; errors caused common shared thought or behaviour, which underestimates, ignores or minimises risks
3. Human
   a. External; human error outside the control span or responsibility of the problem owner
   b. Reasoning; errors caused by the wrong application or the absence of application of knowledge in new situations
   c. Qualification; errors caused by a not permitted difference between training or education of an individual and the relevant task
   d. Coordination; errors caused by a lack of attuned and coordinated tasks between employees
   e. Verification; errors caused by an incomplete or inaccurate judgement of a situation, including the preconditions for the patient and the required materials and appliances, before one starts with the task at hand
   f. Intervention; errors caused by a wrong planning or execution of tasks
   g. Monitoring; errors caused by wrong monitoring practises of a process or patient during the execution of a task
   h. Fine motor skills; -
i. Gross motor skills; -

4. Other
   a. Patient related factors; errors caused by properties of the patient, which are out of the span of
      control of employees but do affect the treatment outcomes
   b. Other; errors that could not be classified in other categories

Of all these categories, now the relation with both devices and procurements is sought. For the first
category, Technical (1), it is without reasoning explained that it is included. This category lists specific
causes of errors that can exist in a medical device that is procured by the hospital. In the procurement
examples in 0, technological causes are recognized in the procurement of beds, syringe pumps and
telemetric devices. During a procurement, these possible errors can be identified.

In the category Organisational errors (2), the sub-categories Knowledge transfer (2b, training program
for the staff, accurate manual), Protocols (2c, is it possible to use this device with the current protocols?)
and Management priorities (2d, is a risk analysis in a procurement performed) are causes that can be
mitigated during procurements.

In the category Human (3), the sub-category Verification (3e, is the right medical device bought for the
specific task?) is a relevant category.

The category Other (4) does not contain relevant sub-categories.

As the amount of identified categories of causes on preventable adverse events, in relation with
procurements, is large (8 in total) and the contributing factors in the causal diagram is even larger, this is
grouped in three categories of causes. The first group is Failures of devices, which represent errors that
are caused by the device characteristics. Categories from PRISMA related to this factor are number 1a,
1b, 1c, 1d, 2b. The second group is failures of interaction use-device, which groups causes that are
coming from the interaction between the user and the interface of a medical device. Failures in this
interaction can come from users and from the device. Categories from PRISMA related to this factor are
number 1a, 1b, ,2b, 2c. The third group is the failures of the organisation, specifically the causes that
could be prevented in the procurement. Categories from PRISMA related to this factor are number 2b, 2c,
2d and 3e. What is specifically not listed here, is failures coming from the user alone. This cause of
failures is not interesting for this research, as it is not something that could be influenced or prevented
with a changed procurement.

These three groups are called factors from now on and are presented in figure 8.3.
§ 8.2.3 Device properties

Here it is assumed that there is a relation between preventable adverse events and preventable deaths. In all publications about patient incidents it is assumed, or proven, that there is a link. This research will also assume that there is a relation, in accordance with reports mentioned in Chapter 1 of Willems (2004), the Institute of Medicine (2000) and Wagner et al (2007). The ratio between the amount of preventable adverse events and the number of preventable deaths is presented by the factor CE risk classification, used in the Regulation for Classification of the law. The CE risk classification contains four classes. The classification is based upon the function the device performs. The more hazard a devices could potentially inflict on a patient, the higher the device is classified.

A factor that is of influence on failures of devices is the well-known mean time between failures. The higher this number is, the less failures of devices there will be. The main time between failures has a negative effect on the costs of maintenance. The more failures there are, the more costs there are made to repair the device. The mean time between failures is influenced by several factors. The first factor, which has a positive influence, is the quality of the device. This is seen as an external factor, influenced by the device producer. The second factor is the age of a device. It is assumed here that the older a device is, the shorter the meant time between failures is. This ignores the fact that there are devices that also have a high amount of failures at the beginning of their life as a result of production errors. The third factor that influences the mean time between failures is the maturity of the technologies in the device. The more a technology is used, researched and applied, the less likely it is that this technology results in defects. For this factor it is also important to look at the combination of technologies in one device, and not only to the technologies on themselves. The syringe pump makes a good example of this. This pump combined technologies of medicine delivery and of wired communication technology. Both are mature technologies, but their combination is not. Then the interface between these technologies is new. This report sees these interfaces between technologies also as a technology. The last factor that has a positive influence on the mean time between failures is the preventive maintenance frequency that is carried out by the LUMC. The maintenance frequency has a positive influence on the maintenance costs.

The last factors that are properties of the device are all factors that are related to factors in other categories. The first one is maintenance costs per device, which is a factor that indicates the costs per maintenance job per device. This is required to calculate the maintenance costs. Also related to maintenance is the factor time per maintenance routine, which has a negative influence on the available treatment time. Then there is the required infrastructure and the required utilities, which indicate in price value the changes for the infrastructure and the utilities (including ICT) that are required. These costs have a positive effect on the factor introduction costs. The requirements come with the device. For example, an MRI scanner needs a lot of changes, for power supply, magnetic shielding, ICT servers and spaces for supporting equipment. It are costs that cannot be ignored in a procurement, as it are necessary costs to make the device operational. Mistakes in planning these utilities can lead to time delays as well as extra costs if no attention is given to these factors. Another example, the ICT requirements for the new EPD requires there to be computers available throughout the LUMC to make patient file accessible. These are additional utility costs related to the procurement of the EPD.

Then there is the price per device, which has a positive effect on the purchase costs. The last factor of the category device properties is interface quality. It indicates how well the interface is made to be understood by the user. This factor positively influences the failures of interaction of user-device. At the moment this is a vague factor that is not quantifiable, not even if it is expressed in more detail. It remains
hard to quantify, as this factor is subjective. Each individual user can and will have a different opinion about the user interface. For this factor to have any meaning, it requires the judgement of a large group of users that assess the interface. A whole research field called User Centred Design is studying this. That field could provide valuable information for the hospital to improve its testing possibilities. For this research that is less relevant, as it looks to the whole system, not just one factor. All these factors and their relation on the other factors are given in figure 8.4.

![Diagram of factors influencing procurement requirements](image)

**figure 8.4** factors of the device properties, and their influence on other factors

§ 8.2.4 Usage characteristics

Usage characteristics groups factors that originate from the use of a device. The usage characteristics contribute to all the possible failures named in § 8.2.2. The description will be started from the factors that are connected with device failures, then the factors that are connected to failures of interaction between user and interface and last the factors connected to failures of organisation.

The factor that is connected to device failures with a positive link is total treatment time. The more treatment hours are made with a device, the more likely it is that the device will malfunction. To determine the total treatment time, this report chose to use the indicators time per treatment and # of treatments. Other possibilities to calculate this are also possible. These two factors are used here as they are factors that are assumed to be possible to estimate for healthcare personnel.

The time per treatment can be estimated by healthcare personnel directly and will represent an average amongst employees. What is ignored here is that the device itself can contribute to the treatment time, by being easy in use, or very hard in use. The # of treatments is positively influenced by the # of departments using a device, and the # of treatments per department. Both can be estimated by healthcare personnel as well, to determine the # of treatments. It also makes it possible in a procurement
to determine at what level a procurement should be governed, as it makes a difference in organisation if 1 or 10 departments are procuring a device.

The three factors that are connected to the factor failures of interaction user-device are \# of treatments, actions per treatment and experience of user. The \# of treatments is already explained in the previous section. The actions per treatment indicate how often an employee actually has to do something for a treatment with a device on a patient. It is assumed here that the more actions are required, the more chance there is to have a failure in the interaction between user and device. Furthermore it is assumed that the experience of a user also determines the chance of a failure in the interaction. The more experienced an employee is, the more he will perform the tasks on a skill based level that requires less conscious focus of that user.

The factors that influence failures of organisation, and which are relevant for this research, are \% of fulfilled requirements and satisfaction with device. \% of fulfilled requirements indicates how effective the device is for the task it is used for. It is disputable if this indicator is more part of the procurement than it is of usage characteristics. Here it is chosen to let it be part of usage characteristics for a good reason. The \% of fulfilment can change over the years by the extra requirements that are needed on the device, something that is changed during use. So the preferences of users change over the years, which effects the \% of fulfilled requirements. This is an important phenomena for three reasons. First of all it influences failures in user-interface interaction. Second, it indicates that during in a procurement the future changes in preferences that are possible in the life span of the device should be anticipated. Third, and less relevant for this research, it is an indicator for an upcoming device wish. The less requirements are fulfilled, the less effective and efficient the device becomes.

The satisfaction with device is a similar indicator as the previous one, but is more orientated on the users of the device, and less on the technology. It has a negative influence on the factor failures of organisation. It is assumed here that the satisfaction of the users with a device is an indicator of how usable the device is for the user. This is positively influenced by the two factors; the \% of fulfilled requirements and interface quality.

Now that all usage characteristics that have an influence on one of the three failures are discussed, some other user characteristics are discussed that are taken into the causal diagram. The first one is the available treatment time. Available treatment time is expressed in hours per year. It is calculated with four factors. The first two were already named under device properties (§ 8.2.3) and are maintenance frequency (negative relation) and time per maintenance routine (negative relation). The third one is the availability of personnel, which is expressed in hours per year as a total of all personnel that can operate the device. The more hours an individual employee is available to operate the device and the more employees are available who can operate a device, the higher the availability of personnel is. The fourth and last factor with influence on available treatment time is the required amount of devices. Increasing the amount of devices will increase the available treatment time.

At the available treatment time has a negative effect on the required amount of devices. It is one of four factors influencing the required amount of devices. The parameter available treatment time is used together with the factors time per treatment (positive relation), total treatment time (positive relation) and peak utilisation (positive relation) to calculate the required amount of devices. The factor peak utilisation indicates a minimum amount of devices that are required to be operational in the hospital to make it possible to cope with certain peaks of demands for medical devices.
The last relations of the factors of usage characteristics are present to calculate costs. In order to make it possible to calculate the factor operational costs, the factors total treatment time and treatment costs per time unit are used here. Both have a positive relation with the factor operational costs. The required amount of devices has a positive influence on the factors maintenance costs, and on purchase costs.

All the factors of usage characteristics are given in relation with the other factors in figure 8.5.

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**§ 8.2.5 Introduction**

The last phase that is discussed here is the introduction. In the introduction the necessary education is provided to the staff of the hospital. Three factors are relevant in the introduction to think about during the procurement. The first factor is the % of personnel trained. The factor is expressed in a % that is calculated by dividing the current amount of trained personnel by the required amount of personnel that needs to be trained. This factor has a negative relation with the failures of organisation, as the higher the percentage of personnel is, the less likely it is that an organisation mistake happens that an untrained staff member operates a device. The % of personnel trained has a negative effect on the factor failures of interaction between user-interface, as the more personnel is trained, the less likely it is that they will make a mistake with the user interface.

The second factor of importance is the training level of users. This is an averaged factor. It is influenced by factor like the training level of the test, the quality of the educator, the intelligence of the user, the attention of the user, and so on. These factors are not listed here, as it out of the scope of this research to improve the introduction process. This factor has a direct negative effect on the factor failures of interaction between user and device. This is a logical explainable relation; the more trained the personnel is, the less likely it is they will misinterpret an interface of a device.
The third and last factor that is part of the introduction is the \texttt{\% of protocols changed}. It is a percentage that is calculated by dividing the changed number of protocols by the total number of protocols that need to be changed. Whenever a medical device is introduced, it is required to review the operational applicable protocols in order to discover procedures in it that are in conflict with the new device. Devices change a working process, so it is very well possible that the protocols need to be changed in order to subscribe a working process.

\textbf{figure 8.6} \hspace{1em} factors of influence on the introduction phase

\textbf{\textnumero\text{ }8.3 Selection of indicative factors for the procurement quality}

In the previous paragraph a causal diagram is made. The design of the diagram is started from the performance indicator preventable adverse events. In this paragraph it is elaborated which factors of the causal diagram influence this performance indicator. First it will be explained which properties are required to have for a factor to be indicative, which is explained in \textbf{\textnumero\text{ }8.3.1}. Then the selection of factors is performed in \textbf{\textnumero\text{ }8.3.2}. The selected factors are discussed in \textbf{\textnumero\text{ }8.3.3}.

\textbf{\textnumero\text{ }8.3.1 Selection procedure}

In this sub-paragraph it is explained how factors are selected that can be used as indicators for a required procurement quality. This selection is performed on requirements.

Two main performance criteria were identified in the previous paragraph, which were the factors of costs and the factor of preventable adverse events. The selection of factors is centred on the factor preventable adverse events. Costs were also reasoned to be performance criteria in the previous paragraph. There is a difference between the costs that are mentioned in the previous paragraph, and the costs for a procurement. From the analysis it was found that the use of resources for a procurement should be limited. These resources for a procurement are not part of the causal diagram, as it is aimed at the introduction and use of a medical device, so neither the costs of the causal diagram are included here.
Many factors in the causal diagram directly and indirectly influence the factor preventable adverse events. For selecting indicative factors for requirements on a procurement process it is important to select factors that can be estimated by the one using the selection process, or at least by personnel in the hospital. The one using these indicative factors is the procurement leader. From a review of procurements (0) that were discussed in the interviews, it has become clear that a procurement leader can be a operational manager of a department or division, a clinical physicist and a specialist. It is very well possible that also high ranked nurses procure items required for the nursing tasks. These function represent three classes of personnel in the hospital.

- The clinical physicists is are not directly connected to the care processes. They represent the first class of procurement leaders, called supportive. The name supportive is chosen, as they are supportive to the core service of a hospital. Other functions within the hospital can be grouped under this as well, for example the departments infra, ICT, VGM, and instrumental services. As they are supportive, they have some knowledge about curing processes, but they are not seen as experts on that terrain. They are seen as experts on the terrains they are active on, like medical physics, ICT, hygiene or ICT.

- The operational managers are not directly connected to the care process. They represent the second class of procurement leaders, called management. The name management is chosen, as they manage the core processes. Other functions within the hospital can also be grouped in this class, for example the purchase department and the direct staff organisations of the executive board. This class has little knowledge about the actual process of providing care, or about the technical side.

- The nurses and specialists are directly connected to the care processes, as they make it possible. They will represent the third class, called executive. This name is chosen as they execute the core service of a hospital, providing care. Other functions within the LUMC can also be grouped in this class, for example surgeons and anaesthetists. Their knowledge is limited to the curing processes they are educated and trained on. In an academic hospital, some of class executive will also be knowledgeable about the medical technologies they research. And some of these researched medical technologies might concern medical devices. Then that executive can also be viewed as a technical expert for the procurement of that specific medical device.

As the groups are so diverse in their background, it is required for the indicative factors not to be subjective. Subjectivity is avoided here by selecting the factors that are as much quantitative defined as possible. Not everything can be quantified. Factors that cannot be quantified must be able to be quantifiable with an objective measurement system.

Another requirement for the indicative factors is the possibility to be estimated. The causal diagram is defined for the period of introduction and use. But here it is used to predict the requirements of a procurement. This requires a future value, which can only be estimated. So the causal diagram is used to estimate the required quality of the procurement. Estimations are more precise when a person carries them out with experience in estimating, when a person is knowledgeable about the factor that is estimated, and when the factor has no other relations with other factors. An estimation carried out by an experienced person requires training. Providing training can be done with the introduction of this framework, but it is out of the scope of this research. A knowledgeable estimate about a factor is possible to achieve by ensuring that the person who is most knowledgeable estimate a number, a range, or even
possible scenarios for the factor that needs to be estimated. The previously named function classes all have their own speciality, so each of these classes can give a good future estimate about certain factors. Estimating factors with no relation requires the selection of factors that have no influence from other factors, or at least are a low number of influencing factors.

In order to select indicative factors, the following requirements are summarized from the text above. The selected factors who are indicative for the quality of the procurement:

1. Must have a direct or indirect influence on the factor preventable adverse events, so to ensure that the primary goal of improving quality is reflected by the selected factor.
2. Should be as objective as possible, so to make an estimate independent of the estimator.
3. Should be as independent as possible, to increase the accurateness of the estimate.

Requirements that are also important, but are not used for selecting indicative factors, are:

- Must be estimated by the one that is knowledgeable about the factor, to ensure that the estimate is more accurate.
- The person or group who estimates a factor should be experienced and trained, so to increase the accuracy of an estimation.

§ 8.3.2 Selection of factors

With the four requirements mentioned in the previous sub-paragraph, now a selection is made amongst the factors of the causal diagram. For this selection a cut-off method is used. A cut-off method implies that whenever a factor does not meet a requirement, it is excluded as an indicative factor. This hard line is chosen so to end up with unambiguous factors as indicators.

The selection of indicative factors is presented in table 8.1. The first column shows the category of the factor. The second column shows the name of the factor. The third column shows the unit of the factor. The fourth, fifth and sixth columns show the score of that factor for requirement 1, 2 and 3.

The first requirement was a direct or indirect influence on preventable adverse events. With help of the causal diagram in figure G.4 it is easy to look up if there is a relation. This provides the answer yes or no. The second requirement required the indicative factor to be objectively measurable. The answer to this is yes or no, with the addition of the category possibly. Possibly indicates that it is possible, but difficult or time consuming, to measure or estimate this in reality. The third requirement requires the indicative factor to be as independent as possible. There are very few factors that are completely independent. Here the causal diagram will be taken as a reference frame. The boundaries of the causal diagram are defined in § 8.1. The answer to requirement 3 is displayed in a number that indicate the amount of direct connection, and the amount of indirect connection between brackets.

Here, the first requirement is answered first. If the answer is yes, then the answer is searched for the second requirement. If the answer is yes or possible, the answer is searched for requirement 3. This is given in a number. The cut-off is at more than 1 direct influence and more than 1 indirect influence. This is arbitrary. These numbers are chosen as then the most independent indicative factors can be chosen. The factors that comply with all three criteria are coloured in green. Some factors in the factor list are good indicators from the view of the requirements from the previous paragraph, but cannot be estimated. These factors are presented in gray. The reasons are:

- The age of a device cannot be estimated in the beginning of a procurement.
• The interface quality cannot be estimated at the beginning of a procurement, as that can only be indicated per device, something that is not possible to measure at the beginning of a procurement.

• The % of fulfilled requirements cannot be estimated at the beginning of a procurement. This factor is a %, calculated by dividing the available requirements by the requested requirements. The requested requirements can be estimated after the program of requirements is finalized, not at the beginning of a procurement. The factor can be useful when selecting a device, as it provides a measure to compare devices.
### Table 8.1: Selection of Factors

<table>
<thead>
<tr>
<th>Category</th>
<th>Factor</th>
<th>Unit</th>
<th>Req1</th>
<th>Req2</th>
<th>Req3</th>
<th># (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device related</strong></td>
<td>Preventable adverse events</td>
<td>events/year</td>
<td>no</td>
<td>yes / no</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Costs per adverse event</td>
<td>€/event</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Image</td>
<td>[scale]</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Preventable deaths</td>
<td>deaths/year</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td>Incident costs</td>
<td>€/year</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Introduction costs</td>
<td>€</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Maintenance costs</td>
<td>€/year</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Operational costs</td>
<td>€/year</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Purchase costs</td>
<td>€</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Influence on incidents</strong></td>
<td>Failures of devices</td>
<td>#/year</td>
<td>yes</td>
<td>yes</td>
<td>2</td>
<td>(8)</td>
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<tr>
<td></td>
<td>Failures of interaction user-device</td>
<td>#/year</td>
<td>yes</td>
<td>possible</td>
<td>6</td>
<td>(2)</td>
</tr>
<tr>
<td></td>
<td>Failures of organisation</td>
<td>#/year</td>
<td>yes</td>
<td>possible</td>
<td>4</td>
<td>(1)</td>
</tr>
<tr>
<td><strong>Device properties</strong></td>
<td>Age of device</td>
<td>year</td>
<td>yes</td>
<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
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<td></td>
<td>GE risk class</td>
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<td>yes</td>
<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Interface quality</td>
<td>[scale]</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Maintenance costs per device</td>
<td>€/device</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Maintenance frequency</td>
<td>#/year</td>
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<td>yes</td>
<td>2</td>
<td>(2)</td>
</tr>
<tr>
<td></td>
<td>Maturity of device technologies</td>
<td>years</td>
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<td>possible</td>
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<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Mean time between failures</td>
<td>hour</td>
<td>yes</td>
<td>yes</td>
<td>4</td>
<td>(2)</td>
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<tr>
<td></td>
<td>Price per device</td>
<td>€/device</td>
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<td>-</td>
</tr>
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<td>Quality of the device materials</td>
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<td>no</td>
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<td>-</td>
</tr>
<tr>
<td></td>
<td>Required infrastructure</td>
<td>€</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Required utilities</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Time per maintenance routine</td>
<td>hour / device</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td><strong>Usage characteristics</strong></td>
<td>% of fulfilled requirements</td>
<td>%</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td># of departments</td>
<td>#</td>
<td>yes</td>
<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td># of treatments</td>
<td>#</td>
<td>yes</td>
<td>possible</td>
<td>2</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td># of treatments per department</td>
<td>#</td>
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<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Actions per treatment</td>
<td># / treatment</td>
<td>yes</td>
<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Availability of personnel</td>
<td>hour / year</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Available treatment time</td>
<td>hour / year</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Experience of user</td>
<td>[scale]</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Peak utilization</td>
<td>#</td>
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<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Required amount of devices</td>
<td>#</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Satisfaction with device</td>
<td>[scale]</td>
<td>yes</td>
<td>possible</td>
<td>2</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Time per treatment</td>
<td>hour / treatment</td>
<td>yes</td>
<td>yes</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Treatment Costs per time Unit</td>
<td>€/hour</td>
<td>no</td>
<td></td>
<td></td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total treatment time</td>
<td>hour / year</td>
<td>yes</td>
<td>possible</td>
<td>2</td>
<td>(2)</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>% of changed protocols</td>
<td>%</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>% of personnel trained</td>
<td>%</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td></td>
<td>Training level of user</td>
<td>[scale]</td>
<td>yes</td>
<td>possible</td>
<td>0</td>
<td>(0)</td>
</tr>
</tbody>
</table>
§ 8.3.3 Judgement of appropriate factors

Here the appropriate factors (marked in green) will be discussed. The group of green indicators is spread into two groups; the first group is immediately useful as an indicator, as it scores positive on all factors. The second group might become useful as an indicator, but is more difficult to measure (requirement 2, outcome = possible). Now the group that is directly measurable is discussed:

greened factors of table 8.1 are reviewed one by one.

- **CE risk class**: The CE risk class indicates the potential hazard a device can inflict on patients, based on the function of a device. The producer assigns a device in a class. The producer is checked by the institute that certifies the medical device and by the national healthcare inspector IGZ. The producer has to classify its devices with the European regulation for classification (Medical Device Directive), with the Dutch counterpart being the *Regeling Classificatie Medische Hulpmiddelen*.

That classification regulation appoints devices in classes based on the risk the function of the device poses to patients. So it is possible for all three classes of procurement leaders, the executive, the supportive and the managing, to look this up, as soon as the functions of a device are known.

- **# of departments**: Buying a device in larger numbers gives the possibility of cost reductions, also during use maintenance. But it does complicate the program of requirements, as more requirements have to be met for the different departments. This factor can be estimated by asking around if other people require a device with a similar function. All three classes of procurement leaders can ask around and estimate the number of departments that use a certain device.

- **# of treatments per department**: The more treatments are carried out with a device, the higher the chance is that an adverse event will occur, be it by a failure of the device or by an failure of interaction between user and device. It is possible to be estimated by an executive procurement leader based on educated guesses, and by other types of procurement leaders by looking at historical data of the hospital.

- **Time per treatment**: the time per treatment is indicative for the factor failures of device. The longer a treatment takes, the higher the chance is that the device will break down. This is especially true for active medical devices and its appliances, opposed to passive medical appliances. This factor thus becomes important when large volumes are procured, as then the factor mean time between failures should be high, so to compensate the increased risk by an increased total treatment time. It even becomes interesting to search for devices with shorter treatment times, with the condition that all specifications are equal to other devices. The executive type of procurement leader alone can estimate this factor. It will be a rough estimation, as the specific device influences the precise number. The other classes of procurement leader would require help of the medical specialists to make a rough estimate.

Here the group of possible to measure factors is discussed:

- **Maturity of device technologies**: The factor displays the maturity of the technologies and combinations of technologies in a specific device from a specific producer. It is possible to measure. Taken strictly it needs to be known for what time the technologies are in use by a specific producer. Furthermore it should be known for how long the combination of technologies is
in use by a specific producer. Only then can it be answered what the maturity of technology is. Taken less strict, it requires the procurement leader to estimate which kinds of technologies he is requesting, and if those technologies, or combination of technologies are new in that type of devices. In other words, it indicates how mature a technology is in a certain market segment of medical devices. And that is something that can be estimated.

For the strict interpretation, the procurement must be at least a phase further than that of assembling a procurement team, as it requires precise answers per device that is a candidate to be purchased. For the less strict interpretation of the factor, it can very well be that it is known that an item is wished for that is new on the market. Then it is possible to use this factor to use it as an indicator of a procurement quality.

This factor is best to be estimated by a procurement leader that has technical knowledge about the device. This can either be someone from clinical technology, or a specialist or clinical physicist who is knowledgeable about the technology by, for instance, his research.

Despite the discussion how strict the factor should be interpreted or who should estimate it, another thing is interesting to mention. This factor is the first one that can be influenced by the specification of requirements. The previous factors could hardly be influenced by the program of requirements, as they were bounded by the function the device would be used for. This factor can become an active requirement. To illustrate this, it can be required that the producer has 5 years of experience in the production of device A with technologies B, C and D.

- Experience of user: The factors are estimated at the beginning of a procurement. Logically, users cannot have experience with a device that is not present in the hospital as it needs to be purchased first. The unit of this factor is defined per device. If one would define this factor to be device class specific, instead of device specific, it could be used as an indicator. But what would it indicate? It could indicate two thinks. First, it is possible that the more experienced a user is with a previous device, the higher the chance is that it will misinterpret the interface of the new device. But that is an error related to the use of a medical device. It is not an indicator of the requirement of the desired procurement quality, except for the requirement that experienced users might need extra training time. Second, the factor indicates how well a user knows which requirements are present for use. The assumption is that the more experienced a user is, the better he knows what the requirements are on a machine. Then it is the key to reveal the requirements, also the ‘obvious’ ones. If the user is not experienced, it is key discover the user requirements.

The question how this is measured is postponed to Chapter 9. That will also answer the question which class of procurement leader should make this estimation and who should seek for help for the estimation.

- Actions per treatment: The number of actions per treatment increases the chance on the factors failures of interaction between user and device. The more actions one treatment requires, the higher the chance of a possible failure. A rough estimator of this factor can be given for the specific functions it requires. This could be based on the care tracks (Zorgpaden) that are being mapped in all Dutch hospitals, although they are not focused on actions per treatment for devices. The precise number of this factor also depends on the device itself, just as with the factor time per treatment.

The factor can be well estimated by an executive procurement leader. The other types of procurement leaders, the managing ones and the facilitators, would require help from users.
• % of changed protocols: This factor is calculated by dividing the number of changed protocols by the number of required to be changed protocols. The first number cannot be estimated, as it is a dynamic number. The second number is hard to estimate in the beginning of a procurement, as the protocols are designed based on (the problems with) the present situation, which requires a device to be present in the hospital. So the second number is also hard to estimate at the beginning of a procurement. Therefore the factor will not be used during procurements. It can be useful for the progress during the introduction and use of a device.

• % of personnel trained: This factor by dividing the number of trained personnel by the number of personnel to be trained. The first number cannot be estimated, as it is a dynamic number. The second number, number of personnel to be trained can be estimated, as it depends on the number of users that will use the device. This is a number that is related to the factors of treatments per division and the number of departments. It is also related by who should perform the functions with the device, the nursing staff, the specialists, or both. Although it is related to the factors number of divisions and the number of departments, it is unique in one way, namely that it indicates if trainings are required, and if yes, for whom. As soon as trainings are required, it is important to think about this in the procurement. Therefore that part of the factor is used as an indicator for the required quality of a procurement.

• Training level of user: This factor can be measured after the education of a user, be it right after education, or periodically after it. The training level of a user requires there to be a notion of the required training level of a user, which should be determined during a procurement as training is usually provided in the introduction of a device. The problem with this factor, is that 'level' is very hard to define for educative skills. It can be made more tangible if it is known what needs to be learned by the users to be able to operate the device. But that requires the procurement leader (or supportive commissions) to know what the user currently knows, and what is required to be known, in order to operate the device. And that will be impossible at the start of a procurement in for most procurements. Therefore this factor is not used.

This paragraph provided a review of factors coming from the causal diagram that make it possible to be used as indicators for the required procurement quality. It is summarized in the next paragraph, which provides the answer to research sub-question 6.
§ 8.4 Answer to sub-question 6

This paragraph summarizes the chapter. The summary provides the answer to:

Sub-question 6: What factors are indicative for the required quality of procurements?

This is answered in table 8.2, which presents a summary of the discussion of § 8.3.

<table>
<thead>
<tr>
<th>Indicative factor</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity of a device technology</td>
<td>Maturity of technology for the whole market segment</td>
</tr>
<tr>
<td>CE risk class</td>
<td>Can be found in the 'Regulation for classification'</td>
</tr>
<tr>
<td># of departments</td>
<td>This must be clear before the specification of requirements is started, as it influenced requirements for the device</td>
</tr>
<tr>
<td># of treatments per department</td>
<td>Based on an educated guess and historical data</td>
</tr>
<tr>
<td>Actions per treatment</td>
<td>Rough estimation, as it is also determined by the device</td>
</tr>
<tr>
<td>Experience of user</td>
<td>Experience with a class of devices. The more experienced, the more important it becomes to identify 'obvious' requirement known by the user</td>
</tr>
<tr>
<td>Time per treatment</td>
<td>Rough estimation, as it is also determined by the device</td>
</tr>
<tr>
<td>Required number of trainings</td>
<td>Coming from factor % of personnel trained. Estimation based on the user groups, # of treatments per department and # of departments</td>
</tr>
</tbody>
</table>

(Blue = device properties; green = usage characteristics; purple = introduction)

The factors are selected from a causal diagram that was built for the system of introduction and use of devices. The factors are selected with a cut-off method, using 3 requirements:

1. The factor must have a direct or indirect influence on the factor preventable adverse events, so to ensure that the primary goal of improving quality is reflected by the selected factor.
2. The factor should be as objective as possible, so to make an estimate independent of the estimator.
3. The factor should be as independent as possible, to increase the accurateness of the estimate.

Requirements that are also important, but are not used for selecting indicative factors, are:

- The factor must be estimated by the one that is knowledgeable about the factor, to ensure that the estimate is more accurate.
- The person or group who estimates a factor should be experienced and trained, so to increase the accuracy of an estimation.

This table answers what factors are indicative, not what they can indicate. They are seen as indicative as they influence the factor # of preventable adverse events and the factor # of preventable deaths. To improve these two factors is the main goal of this research.

In § 8.3.3 it was also briefly discussed which type of procurement leader should estimate factor, based on three types of procurement leaders that were distinguished from examples of procurements. How these factors can be used as indicators is answered in Chapter 9.
CHAPTER 9. A FRAMEWORK TO CLASSIFY PROCUREMENTS

This chapter will answer the main research question, which is:

*How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?*

To answer this research question, two aspects have to be answered. First it needs to be known what forms exist for a procurement team and its supervision and governance. Only when all possible forms are known is it possible to advise a certain form. Second it should be known what the indicative factors can indicate, and how they can be indicative. This makes it possible to select the right form. When these two aspects are clear, they are connected so to make it possible which value of an indicator should lead to what procurement form. With this it is possible to answer the main research question.

This is the first time the terms procurement team and supervision team are used together in this report. Although these terms are unclear now, they will become clear when reading this chapter.

In § 9.1 the approach to define the forms and dimensions of the procurement team are discussed. The § 9.2 and § 9.3 will present explain the forms and dimensions that are possible to identify for the procurement team respectively the supervision team. § 9.4 summarizes the forms and dimensions in a table. In § 9.5 the approach to change the indicative factors into indicators is explained. The following paragraph (§ 9.6) will present the change from indicative factors to indicators. Arguments how the indicative factors can be used as true indicators, and what they possibly indicate. In § 9.7 the construction of a selection model for procurement form is presented. In § 9.8 the answer to the main research question is given.

In this chapter the word expert is used to indicate the users of medical devices and the facilitating departments as described in § 5.1.

§ 9.1 Approach to define forms for the procurement and the supervision teams

As is answered to sub-question 4 (§ 5.4), the formation of the procurement team, its supervision and the governance level should be focused on the involvement of the right experts. Experts take a place in the procurement team or in the optional supervision team. The form of the procurement team exists out of 3 dimensions. Together these 3 dimensions define the form of the procurement team. The same is true for the supervision team. The dimensions are explored in the coming paragraph. In figure 9.1 an analogy of the terms is given in relation with a 3D shape

In the coming two paragraphs the form with underlying dimensions are discussed. The aim is to present the dimensions and to indicate with which unit the value of a dimension should be measured.
§ 9.2 Forms for a procurement team

The procurement team works on different kinds of activities, depending the requirement quality for the procurements. This part discusses the three dimensions there are for a procurement team. Together these dimensions determine the procurement team form. These dimensions are used in § 9.7 to indicate the procurement team form. The dimensions are formation, composition and governance level.

§ 9.2.1 Formation

The first dimension is the formation of the procurement team. The procurement team can have different formation values, which are needed to make it possible to satisfy the need of the executive core not to spend unnecessary resources on procurements, while at the same time it is possible to spend enough attention to procurements that introduce a high risk for adverse events. The formation value indicates how the team members are related to another in the procurement team.

The first possible value is that there is only one team member, the procurement leader. This is possible for low risk procurements. An example that is the procurement of a coagulate time indicator, of which one unit is bought to have an indicator during surgeries of one specific discipline (§ F.6).

The second possible value is that the procurement leader seeks advice from others for the procurement. An example of that is the procurement of cochlear implants. The needs per patient differ, so the kind of required cochlear implants differs as well. The specialist requests advice of audiology experts to verify if the choice for a certain implant is the right one.

The third possible value is that a team of personnel is actively involved in the procurement of a medical device. One example of that is the procurement of telemetric monitoring devices for the cardiology department (§ F.11). For that procurement, the procurement leader, the clinical physicist of the department, requested user expertise from a nurse.

The boundary between the second and the third formation can be vague. For example, what if someone is asked for advice, which then ends up in a couple of discussions between the procurement leader and the advisor? The difference is the intention of involvement. To format a team each member has to be asked and will be active in meeting of the procurement. Someone who is asked for an advice most probably is asked later in the process, is not involved on all aspects and therefore attends a limited number of meetings.
The fourth possible formation is to have a procurement team that seeks for advice from others as well. It can be decided in the beginning to have an advisor later in the process to advise about one specific part. During a procurement it can be discovered that essential knowledge cannot be answered sufficiently by the procurement team. The syringe pump procurement is a procurement in which it was decided in the beginning to establish three separate working groups to form specific requirements for users, technology and medication (§ F.1).

Here a last note is made about the advice, in order to show the diversity of it to the reader. Advice can come internally from individuals and from groups. It can also come from external experts external experts, if no one in the hospital has knowledge. An example of that is the procurement and building of a new intensive care (§ F.9). An external expert was hired to measure and advise about the airflow design in the intensive care.

The formation of the procurement team stands in close relation with the amount of risk a purchase brings in the hospital and with the required knowledge a procurement leader has. The more risk is brought into a hospital, the more experts should be involved. At the same time the experts are not needed in the procurement team all the time, so there is room to ask for advice when it is required.

It is possible to change the formation during the procurement. For example, the procurement leader overestimated its knowledge, so it is decided to form a team later on in the process. Or it is possible that a team cannot work out the specifications for ICT although they expected to be knowledgeable enough, so they seek advice from the ICT department although it was not planned. In short, the future can be planned, but unforeseen events can always occur. A procurement leader may change forms, if there are good reasons present to do so.

§ 9.2.2 Composition based on knowledge requirements

The second dimension is the composition of the team, the areas of expertise that are in the team. The number of experts of the procurement team depends on the required expertise for the procurement and the expertise possessed by the procurement leader. If the procurement leader knows everything needed for the procurement, there is no need to involve other experts. If the procurement leader misses a crucial part of the required knowledge, it is advisable to involve other members. If the procurement leader does not possess the knowledge about less important parts of the procurement, it is possible to acquire this knowledge with an advice from someone not in the procurement team. The possibilities of advice are discussed above with the dimension ‘form’.

The term ‘importance’ is used here to indicate the value that certain tasks have for a procurement. Certain tasks will be less important than others. One can think of the procurement of a laser, in which it is less important to specify the technology behind the laser, but it is crucial to specify what frequencies, intensities and patterns of exposure are required for the treatments. With the procurement of suture it was crucial to develop a user test, in order to verify if the suture in reality works as it should, and if the users are satisfied with the characteristics of the new suture. So it is possible to distinguish in a procurement that certain tasks or information needs are more important than others. This is a rank of the tasks and information needs for the procurement. Another factor that influences the importance of tasks and information, which is the risk the device brings into the hospital. This influences the whole importance of tasks of the procurement.
§ 9.2.3 Governance level

The procurement team is an operational group that has to carry out certain tasks. The procurement leader should have the right level of governance so he can manage that procurement team. Especially for a professional bureaucracy like the LUMC, is it important to have an equal or higher ranked procurement leader, so that the authority is unquestionable on the aspect of hierarchy. The governance level of the procurement leader is thus chosen based upon the level of the other required members in the procurement team, so to avoid conflict of ranks.

It is explicitly chosen not to increase the governance level based on the risk a device will have for the hospital. It is believed that increasing the knowledge of the team (the former dimension) is a much better measure to counter risks for patients than installing a higher ranked procurement leader. A higher ranked procurement leader will be more detached from the actual working processes, making him or her less useful to lead a procurement that introduces high risks, as he or she does not have operational knowledge. The responsibility of the content of what is done is for the procurement team.

There is no need to increase the level of governance from department, to division to central levels, along with the increasing risk. The managers both on a division or central level cannot make a contribution to the procurement team, as they have not have operational expertise, except from organisation skills. Therefore the level of governance for procurement teams is searched from within the department themselves. Within the departments one can find the real experts, who have the proper knowledge and hierarchical level to be the procurement leaders.

The value of a purchase is not an indicator for this research, but it is imaginable that the higher the value is, the more there is a need for a procurement leader with more authority and managerial skills.

§ 9.3 Forms for supervision

A supervision team can supervise a procurement team. The task of the supervision team depends on the required level of supervision. The general idea (explained in § 9.7) is that the more risk on adverse events, the more the supervisor(s) are involved. To make supervision possible it must be possible to control the procurement team. A planning must be present, which states what is done to achieve a desired outcome at a certain moment in time.

The supervision form has three dimensions, which are involvement, formation and governance.

§ 9.3.1 Involvement

The first dimension is involvement of the supervision team. This dimension can have three values, namely no involvement, procedural involvement and substantive involvement. No involvement means there is actually no supervision present. Supervision is not necessary for low risk purchases.

The second value is procedural involvement. Procedural involvement here means that the supervision team is only controlling if all planned work is done. The supervisors can request an explanation if a change in the planning is not acceptable.

The third value is substantive involvement. Then the supervision team fulfills not only the tasks for procedural supervision, it also challenges the outcomes of processes on the key decision moments. One can think of the program of requirements, selection algorithms and outcomes of user tests.
§ 9.3.2 Composition

The supervision team has a different role than the procurement team. The procurement team is focused on the content of the procurement. The procedural supervision team is mostly concerned with the process of the procurement. Therefore the supervision team should have knowledge to supervise the procurement processes. Then the supervisors can quickly understand a situation based on experience, and possibly warn about potential pitfalls.

For the substantive supervision it is also important to make it able for the supervision team to understand the outcome of processes and to interpret the possible consequences. Only then is it possible for the supervisors to challenge the outcomes of processes, something that is necessary for procurements that introduce a high risk for adverse events. The substantive supervision requires supervisors that possess knowledge about project work and other supervisors that possess knowledge about the content of the procurement.

§ 9.3.3 Governance level

The thought for the governance level is that the higher the risk for the hospital becomes, the higher the governance level should be. The higher the governance level is, the shorter the communication to the executive board is. The executive board is the end responsible for the hospital. This shifts the responsibility of the governance to higher levels as soon as there is a need for it, a need that is based upon the risks for patients. The level of governance is only applicable for the supervisors that are responsible to control the whole process of the procurement. The expertise to challenge the outcome of procurement activities most likely comes from the specialists in the field.

There are three different governance levels visible in the hospital, which are the department, the division and the central level. Those are the values for supervision governance level. Here an additional level is defined, which is multi-division. This is defined for procurements between multiple divisions, but with a risk that does not require a central supervisor. Then it is wise to have supervision from several divisions, as the responsibilities during use are also spread over these divisions.

§ 9.4 Diagram of possible forms for the procurement and supervision team

The previous paragraph presented the main possible forms of a procurement team and the supervision team. Both teams have three dimensions that determine form. The possible value of each dimension was discussed, together with the basis to decide upon a certain value. This is summarized in table 9.1.

<table>
<thead>
<tr>
<th>Team</th>
<th>Dimension</th>
<th>Values</th>
<th>Choice based upon…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement</td>
<td>Formation</td>
<td>One, One+advice, team, team+advice</td>
<td>a. Risk for adverse events</td>
</tr>
<tr>
<td></td>
<td>Composition</td>
<td>[Required expertise]</td>
<td>b. Required amount of time per expertise</td>
</tr>
<tr>
<td></td>
<td>Governance</td>
<td>[Ranks within department]</td>
<td>c. Knowledge gap between procurement leader and required knowledge</td>
</tr>
<tr>
<td></td>
<td>level</td>
<td></td>
<td>d. Rank of involved experts</td>
</tr>
<tr>
<td>Supervision</td>
<td>Involvement</td>
<td>None, procedural, substantive</td>
<td>e. Risk for adverse events</td>
</tr>
<tr>
<td></td>
<td>Composition</td>
<td>[Required expertise]</td>
<td>f. Risk for adverse events</td>
</tr>
<tr>
<td></td>
<td>Governance</td>
<td>Department, division, multi-division, central</td>
<td>g. Involvement level</td>
</tr>
<tr>
<td></td>
<td>level</td>
<td></td>
<td>h. Risk for adverse events</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>i. Required level of cooperation</td>
</tr>
</tbody>
</table>
§ 9.5 Approach to transform indicative factors into indicators

In Chapter 8 it was determined that a total of 8 indicative factors need to be used to determine the required quality of the procurement. For these indicative factors to become meaningful and useful in practice, it needs to be determined in which unit these factors are measured, and in which bandwidth a value for a factor could fall. By determining the unit, it becomes possible to develop a measurement method by the hospital. By determining the bandwidth, it becomes possible to indicate levels within the bandwidth that can be used to indicate levels of risk.

The table 8.2 is repeated to present the 8 indicators again (table 9.2). With the unit and bandwidth together it is possible to indicate risk levels, which is the input in § 9.7 to develop a selection model based on risk. The next paragraph (§ 9.6) discusses each factor separately and indicates the unit and its bandwidth.

### Table 8.2

<table>
<thead>
<tr>
<th>Indicative factor</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity of a device technology</td>
<td>Maturity of technology for the whole market segment</td>
</tr>
<tr>
<td>CE risk class</td>
<td>Can be found in the 'Regulation for classification'</td>
</tr>
<tr>
<td># of departments</td>
<td>This must be clear before the specification of requirements is started, as it influenced requirements for the device</td>
</tr>
<tr>
<td># of treatments per department</td>
<td>Based on an educated guess and historical data</td>
</tr>
<tr>
<td>Actions per treatment</td>
<td>Rough estimation, as it is also determined by the device</td>
</tr>
<tr>
<td>Experience of user</td>
<td>Experience with a class of devices. The more experienced, the more important it becomes to identify 'obvious' requirement known by the user</td>
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<tr>
<td>Time per treatment</td>
<td>Rough estimation, as it is also determined by the device</td>
</tr>
<tr>
<td>Required number of trainings</td>
<td>Coming from factor % of personnel trained. Estimation based on the user groups, # of treatments per department and # of departments</td>
</tr>
</tbody>
</table>

(\text{blue} = \text{device properties}; \text{green} = \text{usage characteristics}; \text{purple} = \text{introduction})

§ 9.6 Transforming indicative factors into indicators

This sub-paragraph presents for each unit its value and the bandwidth. This is required for the user to let him understand what value he has to fill in for each factor. The bandwidth provides a possibility for the user to choose from. The bandwidth of each factor depends on detailed information of the hospital, which is not collected in this research. It is still open for the hospital to specify it in detail. The designation of risk levels within each bandwidth is open as well.

**Maturity of a device technology**

**Unit:** The unit of maturity was already discussed in § 8.3.3. It was concluded there that this factor could only be estimated for the whole market segment, as not yet a specific device is selected in the beginning of the procurement. Furthermore it was explained that it is possible to use this indicator to state demands in the requirements specification, for example "producers should have at least have 4 generations of experience with technologies A and B in combination with device type X".

Here it is not about stating demands in a program of requirements, but estimating how mature the technologies and combination of technologies used in a device are. Maturity can be expressed in several units. The units that are discussed here are ‘generations’, ‘years’, and ‘product life cycle status’. 
Chapter 9  A framework to classify procurements

The unit ‘generations’ indicates the number of the generation of a device. But that differs between producers, as the early producers went to more generations than the producers that entered the market later. Next to that, the number of generations does not have to indicate anything about the chance on adverse events with a device. A new producer may have a product with radical new improvements.

The ‘number of years’ certain (combinations of) technologies are in use in a device is an absolute indicator for the maturity of a device technology. But it is impossible to use this as an indicator, as there is no absolute meaning for the answer 2 years. This number should be seen relative to its market development to become useful, which has to be discovered for each technology again.

Therefore the unit of ‘product life cycle’ becomes more interesting to use. The term originates from marketing research. The product life cycle (PLC) defines the course that a product sales and profits take over the years. Although it is concerned with sales and profits, the life cycle stages that are recognized are useful to recognize the maturity of a certain device type. PLC theory recognizes 5 distinct phases, which are development, introduction, growth, maturity, and decline (Kotler, Armstrong, Saunders, & Wong, 2001, pp. 518 - 525). The development phase is defined to have no sales, so that is a category that is not relevant for the hospital. In the introduction phase the growth of sales is low, so the market penetration is low as well. The growth phase has the highest growth of sales, and market penetration is increasing. In the maturity phase the sales growth rate declines and turns negative, while the market penetration comes at the maximum, and consumers start replacing devices. The decline rate shows a decline of sales rate and a decline of sales, while the market penetration of the product stays the same or even diminishes. The four phases that are applicable to the hospital can become indicative. It is possible for a procurer to study the market and discover that a product is in a certain phase.

**Bandwidth:** The bandwidth is already named above. It ranges from ‘introduction’ until ‘decline’.

**CE risk class**

**Unit:** The unit of the CE class is the risk class. The existence of the classification can be found in the Dutch laws named Decree Medical Appliances, and Regulation for Classification of Medical Devices. It is discussed in detail in Appendix D and Chapter 8.

**Bandwidth:** The bandwidth falls into the four classes, Class I, II/a, II/b and III.

**# of departments**

**Unit:** The unit is clear, it is departments. One organisation addition to this unit should be the number of divisions, as this changes the governance level of the supervision. So additionally the unit divisions added, so to ensure that the governance level of the supervision can be indicated.

**Bandwidth:** As the LUMC contains 50 departments, the bandwidth is between 1 and 50. Furthermore the LUMC contains 6 divisions, making the bandwidth for the number of divisions between 1 and 6.

**# of treatments per department**

**Unit:** The unit is treatment per departments, measured per year. To estimate a risk level, it should be known what the maximum number of treatments per year could be. This research did not research the maximum number. It is up to the hospital to make an estimation what could become indicative for the risk.

**Bandwidth:** The bandwidth of this factor lies between 1 and a certain maximum. This maximum is not known nor researched here. For this factor to be used in this research, here the simplified scale of rare,
average and frequent is used. This scale can be translated by the hospital that adapts this framework. The art then is to fill in what is seen as rare, average or frequent.

**Actions per treatment**

**Unit:** Actions per treatment is already a clear unit. The higher the value is, the higher the chance on an adverse event.

**Bandwidth:** The bandwidth of this factor lies between 1 and a certain maximum. This maximum is not known nor researched here. For this factor to be used in this research, here the simplified scale of low, medium, high is used. This scale can be translated by the hospital that adapts this framework. The art then is to fill in what is seen as low, medium or high.

**Experience of users**

**Unit:** In the causal diagram this factor has a negative relation with the factor failures of interaction user-device. In § 8.3.3 it was determined that this factor can be used predictive on the knowledge level of users with the new device. Furthermore it would be useful as an indicator to estimate how well a user could estimate its own requirements. The thought behind it is that the more experienced a user is, the more that user knows what he needs. One remark here is that it becomes important to determine the needs that are seen as obvious by the user, as also obvious needs should be in the requirements.

An experienced user might also be more likely to misinterpret the interface of the new device, based on assumptions of an older similar device. On the other hand it is possible that the experienced user knows a lot about what can be expected of a device, making it less likely to make errors while operating the device. Whether experience increases or decreases the chances of failures of interaction between user-device depends on a large number of variables. That is not under study here, so it is left aside for further research.

What is used as indicative from this factor, is that the more experienced a user is with aspects of a new device, the better that user is capable of specifying its own requirements, as long as that user is alert to think of the obvious requirements as well.

**Bandwidth:** Experience level can be measured on a scale, indicated with by the outcome of a test, or by the time the user has been working with it. Whether the hospital prefers a test or an educated guess of the time a user has been working with a certain device type, it can be classified in three steps of low, medium or high. The experience level should be measured by the hospital. This can be translated in a scale of low, medium and high.

**Time per treatment**

**Unit:** The time per treatment can be indicated in seconds, minutes, hours or days. It does not matter which time unit is chosen, as it all has the same value. From the causal diagram it is learned that the longer the treatment time, the higher the chance of a failure of that device. The treatment time will differ between the users, but also between devices. As is explained in § 8.3.3, only a rough estimate is required.

**Bandwidth:** The time per treatment is expressed on a four step scale, of seconds, minutes, hours or days. To illustrate, if a treatment takes 6 hours and 30 minutes, it is part of the step hours.
**Required number of trainings**

**Unit:** The required number of trainings is an indicator coming from the factor % of personnel trained. It is used to indicate if, and how many trainings are required. This is indicative on the number of users that are going to use a device. The purpose of this requirement is to think of trainings in the procurement, so its main purpose is make sure that the procurement team plans to provide trainings during the procurement. Its indicative value on risks is low, but trainings are an important measure to lower the number of adverse events.

**Bandwidth:** This is a number that can be up to the total number of doctors and nurses combined.

**Summary of paragraph**

This paragraph turned the indicative factors into indicators, by providing the bandwidth and the unit of measurement were possible. For some indicators it is impossible to indicate a number in this research, as that should come from statistics from the hospital that are not available in this research. Defining the bandwidth in detail for only the LUMC would also hinder the use of the model in other hospitals. So some factors have a three-stepped scale of low, medium, high, which should be made more applicable by hospital experts before using it. The indicators and their bandwidths are given in table 9.3.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Bandwidth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity of a device technology</td>
<td>Introduction, growth, maturity, decline (from life cycle approach)</td>
</tr>
<tr>
<td>CE risk class</td>
<td>I, II/a, II/b or III</td>
</tr>
<tr>
<td># of departments</td>
<td>between 1 and 50, with the addition of the number of divisions</td>
</tr>
<tr>
<td># of treatments per department</td>
<td>rare, average, frequent</td>
</tr>
<tr>
<td>Actions per treatment</td>
<td>low, medium, high</td>
</tr>
<tr>
<td>Experience of user</td>
<td>low, medium, high</td>
</tr>
<tr>
<td>Time per treatment</td>
<td>seconds, minutes, hours, days</td>
</tr>
<tr>
<td>Required number of trainings</td>
<td>-</td>
</tr>
</tbody>
</table>

*(blue = device properties ; green = usage characteristics ; purple = introduction)*

§ 9.7 A model to select the right procurement form

As is seen in figure 7.1, the mean ‘assign knowledgeable procurement leader’, supports many other means. To make the procurement leader more knowledgeable, here a selection model is developed that provides an advice on how to form the procurement team and the supervision team. To develop this model, the indicators of table 9.3 and the different forms for procurement teams and supervision of table 9.1 are connected with a framework. This is illustrated in figure 9.2.

For the development of the framework it is necessary to develop a system to connect the indicators to a certain risk level, which leads to a choice of a form for the procurement. In § 9.7.1 and § 9.7.2 it is explained how the values of the indicators can be used to judge the risk level. In § 9.7.3 and § 9.7.4 it is explained what form is required depending on this risk level, for the procurement team respectively the supervision team.
§ 9.7.1 Judgement of risks with indicators; approach

A mathematical approach is appropriate to use to judge a risk level as that provides a possibility to distinguish unambiguous between risk classes. To make a mathematical model that judges a risk level, two different approaches can be used. First, it is possible to classify the risk on adverse events as high whenever one of the eight factors in table 9.3 is at the threshold value. This is a stepwise approach of judging risks. Second, it is possible to classify the risk on adverse events with a gradual approach, in which the risk on an adverse event is chosen based upon the sum of all factors.

Compared to the gradual approach, the stepwise approach results in a framework that leads to more controlled procurements and more costs. Compared to the stepwise approach, the gradual approach results in a framework that leads to less controlled procurements and fewer costs.

Here it is chosen to use a gradual approach for two reasons. The first reason is that the stepwise approach will lead to an unacceptable framework. It is believed that the executive core will not accept a framework that results in a full featured procurement, just because one factor (such as the risk class) has a maximum value. The second reason is that the gradual approach better reflects the nature of the causal diagram in figure G.4. In that causal diagram it is visible that all factors contribute to the number of adverse events.

§ 9.7.2 Judgement of risks with indicators; scoring tactics

To judge a risk level, each possible value of an indicator must receive a score. This score creates a relative difference between the possible values for one indicator. To indicate the score of the indicator opposed to other indicator, each indicator should also have a weight attached to it. This creates an absolute score of all indicators opposed to another.

Filling in the weights for the indicator is an essential step for the completion of the risk assessment form. As it is such an essential step, it deserves more attention than is available in this graduation project. The choice should be substantiated, by thorough discussions with and between the decision makers on various levels of the LUMC, or any other hospital that adapts this framework. Over the years it should be possible to change the weights, based on experience of the relative importance of indicators amongst another. The weights should not be changed per procurement, as that makes the assessment of a risk level not comparable between procurements.

The table 9.4 shows the risk assessment form. The table is explained here per column from left to right, for how it should be used by the procurement leader. Column 1 and 2 are already explained in table 9.3. In column 3 the score of each indicator has to be chosen. The score should fall within the bandwidth, for the reason that it should be possible to normalize the score. Normalizing means that a certain score in a certain bandwidth is given a value between 0 and 1. The normalisation makes it possible to weight the indicators, for the reasons explained above. In column 4 the normalized score of each indicator is written down. The weights per indicator are given in column 5. These are constant over all the procurements, for the reasons mentioned above. In column 6 the multiplication of the normalized score and the weight per
factor are written down. The sum of all the normalized, weighted scores of the indicators is written in the lowest cell.

This score will fall in a bandwidth that is between 0 and the sum of the maximum normalized weighted score of all indicators. In the next sub-paragraph a total of 4 risk levels are chosen. The sum of the normalized, weighted scores will fall in one of the four categories. The distribution of the four categories can be evenly distributed over the whole bandwidth, but other distributions can be possible as well.

### Table 9.4 Risk assessment form to calculate the risk score based on 8 indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Bandwidth</th>
<th>Score per indicator</th>
<th>Normalized score per indicator</th>
<th>Weight per indicator</th>
<th>Normalized weighted score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity of a device technology</td>
<td>Introduction, growth, maturity, decline (from life cycle approach)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CE risk class</td>
<td>1, 2a, 2b or 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No of departments</td>
<td>between 1 and 50 with the addition of the number of divisions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actions per treatment</td>
<td>low, average, frequent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience of user</td>
<td>low, medium, high</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time per treatment</td>
<td>seconds, minutes, hours, days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required number of trainings</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Legend: blue = device properties; green = usage characteristic; purple = introduction property)

### § 9.7.3 Required form for the procurement team in relation to the risk

The previous sub-paragraphs defined how it is possible to indicate a level of risk on adverse events. With this level of risk it is possible to indicate what is required form the procurement team should have, defined for all three dimensions.

For the dimension formation it is straightforward; the higher the risk is, the more experts should be involved. This is made visible in table 9.5. Involving experts increases the likelihood that processes in the procurement lead to high quality outcomes, which in the end should lead to less adverse events with medical devices.

The dimension composition of the procurement team depends upon the knowledge gap between the procurement leader and the required knowledge for the procurement. The less the procurement leader knows, the more help is required from others.

As a definition, it is true that if only one person carries out the procurement, because of a low risk for adverse events, it is not required to think about the required expertise, as that should be present at the one person. When a procurement is seen as high risk, automatically a team is formed that is supported by advising groups. So although the procurement leader may think he knows everything about the procurement there possibly is, the advice will be to work together with others.

The dimension governance level of the procurement leader should be chosen to be at least equal to that of the other team members, to avoid possible conflicts of ranks. The required rank of the procurement leader is dependent upon that of the other experts that are involved.
§ 9.7.4 Required form for the supervision in relation to the risk

In § 9.7.1 and § 9.7.2 it is defined how a level of risk on adverse events can be indicated. With this level of risk it is possible to indicate what the required form is for the supervision team.

The first dimension is the involvement of the supervision team. This is based on the level of risk. The higher the risk is, the more involved the supervision team should be, which is indicated in table 9.6. This ensures that the procurement team is controlled more thoroughly whenever the risk increases.

The second dimension is the composition of the procurement team. That stands in close relation with the involvement. If the involvement is only procedural, the required expertise will only be required for checking up on the procedures. But if it is required to have substantive involvement, content experts should also be involved.

The third dimension is the governance level. The governance level is dependent on two factors.

First of course the risk level. The higher the risk level, the higher the governance level should be chosen. Then the responsibility is moved towards the executive board, which is in the end responsible for the safety of patients in the hospital.

The second on which the governance level depends is the level of cooperation. The general thought is that managers from a higher level should always supervise the cooperation between departments, so that it is possible to solve internal conflicts. If a large procurement is done for two departments in the same division, it is wise to have supervision present on a division level, to make it possible to have an authority present that can decide upon internal problems in the procurement. If the cooperation is between two departments of different divisions, it is advised to that the division managers to take place in the supervision team, so that they can discuss about problems. The central level is also advisable for procurements in which several departments in several divisions are involved, even if it is not such a high risk procurement.
§ 9.7.5 Summary

This paragraph provides a framework that makes it possible to base the establishment of the procurement team and the supervision team on the estimated risks a procurement brings into the hospital. First a scoring system was developed. The scoring system is not completed, as it requires input from the executive core of the hospital. The scoring system makes it possible to classify a procurement in a level of risk.

For a certain risk level it can be determined what values are advisable to use for the three dimensions of formation, composition and governance level for the procurement team (table 9.5). Additional information is required to determine the composition. It needs to be known what the knowledge gap is between the required knowledge and the knowledge of the procurement leader. For the governance level it needs to be known what ranks the experts have, to avoid that the procurement leader is not an equal to the other experts.

For a certain risk level it can be determined what values are advisable to use for the three dimensions involvement, composition and governance level of the supervision team. (table 9.6). Additional information is required for the composition of the supervision team. It needs to be known what the involvement level is, so it can be determined which expertise is required for the composition. For the governance level it needs to be known how much departments and divisions are active in the procurement. The aim is to choose a governance level that is above the departments and the divisions, so that the supervision team can solve internal conflicts.

§ 9.8 Answer to the main research question

This chapter provided a framework that guides the procurement leader in its decision to form a procurement team and to establish supervision. This whole chapter answered the main research question, which is:

How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?

In order to improve the procurement of medical devices, the formation of the procurement team and its supervision team should be improved (sub-question 4). As there is a trade off to be made between the required quality of the procurement and the amount of resources spent on procurements, it is chosen to make adaptive procurement team forms and supervision team forms. This requires it to be clear what different forms are present, how risk is measurable, and what the connection is between the risk level of a medical device during use and forms for the procurement and supervision team:

- The forms of the procurement team and the supervision team are distinguished. The form of the procurement team is made up out of three dimensions, which are the formation, the composition and the governance level. All three dimensions can have different values, which are given in table 9.1. The form of the supervision team is made up out three dimensions, which are the level of involvement, the composition of the supervision team and the governance level. All three dimensions can have different values, which are given in table 9.1.
Also the measurement system of risk is developed. From each of the eight indicative factors the measurement unit and the bandwidth of the outcome of the unit is determined, which is summarised in table 9.3. To judge a risk level, a mathematical approach is appropriate to use, as that provides a possibility to distinguish unambiguously between classes. It is chosen to base the risk on the sum of the indicators, not on the highest score amongst the indicators. This provides a score that does not escalate a procurement to high risk too quickly, and it represents the causal diagram well. With the sum of the indicators and the bandwidths for each dimension it is possible to normalize and weight factors, making it possible to increase or decrease the importance of certain indicators. This is not filled in here. It is up to the hospital to assign weights to indicators.

The connection between the risk level of a medical device during use and forms for the procurement and supervision team are explained here. It is chosen to group the risk scores in four levels, as the possible values of the dimensions of the forms of the procurement team and supervision team are also limited to four. If in the future the possible number of values for a dimension changes, the risk groups should change accordingly. The outcome of this system that links the potential risks of a procurement on adverse events with the advised form of a procurement team and a supervision team is given in table 9.7. This framework can be used by the procurement leader to base its decision on for the required forms for the procurement and the supervision team.

<table>
<thead>
<tr>
<th>Risk during use</th>
<th>Procurement team</th>
<th>Supervision team</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formation</td>
<td>Composition</td>
</tr>
<tr>
<td>Low</td>
<td>One</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>One + advice</td>
<td>Team</td>
</tr>
<tr>
<td></td>
<td>Team + advice</td>
<td>[Ranks within department]</td>
</tr>
</tbody>
</table>

Table 9.7  A framework that connects procurement form with risk level during use
Chapter 10 Conclusion

This research focused on procurements of medical devices by the LUMC, an academic hospital in Leiden. The problem owner, the executive board, is responsible for the well being of patients in the hospital. The current procurement process does not support the procurement of safe medical devices, so the process of procurements required improvement. The dilemma for the problem owner is found in the use of resources, which are believed by the executive core to be better spent on healing patients than on procurements. The improvement needs to be acceptable. This leads to the main research question:

How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?

A total of six sub-questions were formulated to make it possible to answer the main research question. The answers to the sub-questions are given first, before answering the main research question.

1. What is the definition of ‘medical device’? (Chapter 2)
   The answer is found with a desk research of Dutch Laws:

   Any instrument, apparatus or device, any substance or other article, alone or in combination, including the required software for its proper functioning, and that it is intended by the producer to be used with humans for the following purposes:
   - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - Diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,
   - Investigation, replacement or modification of the anatomy or a physiological process,
   - Control of conception,
   For which principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but such appliances can support this.

2. What is seen as a qualitative good procurement? (Chapter 2)
   The answer to this research question is found with desk research of the Dutch Law and publications of professional organisations. The NIAZ and NVKF have formulated criteria for quality of procurements:
   - The hospital has a regulation for the procurement of all the kinds of goods that are used within the institute. This regulation specifies the following points:
     - The way how experienced employees are involved in the selection process, if the procurement is for goods or devices used in the healthcare processes
     - The way in which the selection and judgement of the suppliers of goods is carried out
   - The hospital has regulation for the process of risk analysis in the beginning of a procurement of (medical) devices, meant to guarantee the quality during use [part of NTA 8009:2007].
   - The total device inventory in the hospital is classified in risk classes based upon applied risks analysis.
   - All devices are procured on basis of predetermined investment budgets and predetermined procurement processes.
3. How is the current procurement for medical devices? (Chapter 4)
This is answered by interviews with 19 persons in the LUMC. The presentation of the data from interviews was structured using a conceptual diagram, with four distinct phases within the procurement:
1. Formation of a procurement team
2. Specification of the requirements
3. Selection of a supplier
4. Acceptation of the device and payment

For the phase formation of a procurement team it was found that no policy is in use to form this team. At the moment the facilitating departments all have unofficial connections, meetings and systems in use to involve themselves on time, or at least before payment, in the procurement so to prevent wrong procurements.

For the phase specification of requirements it was found that no regulation for specification was named, except for the European tenders (> € 250k). Especially for small procurements (< € 100k) no indication was found that regulation is present, let alone in use. Risks analyses during procurements are hardly performed. A risk classification system is present, but it is not updated since its introduction in 2004, which questions the applicability of the method.

The phase selection of suppliers is structured for European tenders. But again, no such structure seems to be prescribed for the lower budget procurements.

The phase acceptation of devices is performed by the clinical technology department, which only checks active medical devices. No acceptation tests are performed for passive medical devices.

Findings concerning all phases of the procurements were also recognized. The commission for the quality system of medical devices is not functioning, as it develops policies on a central level, which are not taken into work processes on a local level. The commission has no mandate to force people to work with the protocols. Next to that, the facilitating departments are all of opinion that risks should become more visible for the users, so they can act on these risks.

4. What part of the current procurement should be improved? (Chapter 5)
This sub-question is answered by analysing sub-question 2 and 3. It was learned that three parts needed to be improved:
1. Prescribe regulation how experts are involved in the procurement process
2. Prescribe regulation that indicates how the selection of suppliers should be carried out
3. Prescribe how a risk analysis during procurements should be carried out

The first point is further researched, as that is the key for solving the other two problems as well. Without involving the right experts, it is not possible to make a good selection of suppliers or perform a useful risk analysis.

5. What are possibilities to improve the quality of a procurement? (Chapter 7)
Procurement quality is defined as the degree in which the goal of providing a safe environment for patients and personnel with devices during use is reached with the procurement.
The answer to the sub-question was sought using desk research and a creative analysis process. The literature on procurements for medical devices or procurements in the service industry\(^\text{14}\) is not present yet. Hospitals themselves are only recently interested in improving their purchase processes, with the goal of improving safety, and the research literature does not yet exist. A literature review of supply chain management theory provided a lot of information about procurements. But the only goal for procurements was reducing costs. There was no goal described that aimed to decrease risks. For this research that literature is therefore not useful.

The development of possibilities to improve the procurement quality is performed with use of the information of the interviews and creative analysis. The results are shown in an end-means diagram (figure 7.1), a diagram that shows how the end - improving the quality of a procurement – is supported by means, or measures, and how the measures support another.

6. **What factors are indicative for the required quality of procurements?** (Chapter 8)

For answering this research question, a causal diagram of the system of medical devices during use is constructed. The causal diagram shows the factors that are of influence on the factor ‘preventable adverse events’, in relation with medical devices. The causal diagram was used to find factors that could be used as indicators for the required quality of the procurement. The factors were found if they complied with three criteria:

1. The factor must have a direct or indirect influence on the factor preventable adverse events, so to ensure that the primary goal of improving quality is reflected by the selected factor.
2. The factor should be as objective as possible, so to make an estimate independent of the person who estimates.
3. The factor should be as independent as possible, to increase the accurateness of the estimate.

With these three criteria the factors out of the causal diagram were selected that are indicative for the required procurement quality. These factors are:

- **Maturity of a device technology**, how long a technology is on the market at any given producer
- **CE risk class**, a factor that is categorized by the European Medical Device Directive
- **# of departments**, based upon the departments that require the medical device
- **# of treatments per department**, based on an educated guess and historical data
- **Actions per treatment**, a rough estimation is the best possible, as it is influenced by the device
- **Experience of user**, with a certain device type. The more experience, the more requirements can be known by that person
- **Time per treatment**, a rough estimation is the best possible as it is influenced by the device
- **Required number of trainings**, a estimation based upon user groups, the # of treatments per department and the # of departments

\(^{14}\) A hospital is seen as part of the service industry
With the answers to the sub-questions is it possible to answer the main research question (Chapter 9):

*How can the procurement of medical devices be improved by means available for the executive board, in order to increase the quality of the medical device during use, while remaining acceptable for executive core?*

By the executive core ‘acceptable’ is seen as being neither bureaucratic nor consuming too much time. The solution is bounded by these demands from the executive core. This creates a trade off between procurement quality and procurement resource use. Therefore a framework for adaptive involvement of experts is chosen as the solution to this problem. The framework advises the procurement leader on the establishment of a procurement team and supervision team, based on the possible risks for patients and personnel during use of a medical device. If the risk is low, there is no need to use valuable time of experts in the procurement process. The framework will then advise not to involve experts. If the risk is high, the framework will advise to involve experts. The involvement of experts is righteous if the risk is high. The involved experts provide a basis for the rest of the course of the procurement process to evade or mitigate risks that are introduced with the new medical device. The framework is shown here:

*framework to determine the required form of the procurement team and the supervision team, based upon the potential risk of adverse events with the use of a medical device*

<table>
<thead>
<tr>
<th>Risk during use</th>
<th>Procurement team</th>
<th>Supervision team</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formation</td>
<td>Governance level</td>
</tr>
<tr>
<td>Low</td>
<td>One</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>One + advise</td>
<td>[Ranks within department]</td>
</tr>
<tr>
<td>High</td>
<td>Team</td>
<td>Substantive</td>
</tr>
<tr>
<td></td>
<td>Team + advise</td>
<td></td>
</tr>
</tbody>
</table>

As is shown in the framework above, experts can take place in the procurement team or the supervision team. The procurement team is an operational team that will be active in the requirement specification, risk analysis, selection of a supplier, user tests, acceptance tests and forming contracts. The formation of the procurement team depends on the risk coming with a medical device and on practical considerations such as if an expert is available. The higher the risk, the more experts should be involved, be it in the procurement team or as advisors. The composition of the team depends upon the required expertise for a successful procurement. It is up to the procurement leader to determine the required expertise. The governance level of the procurement leader should be equal or higher than that of the other team members to avoid conflicts of rank. It is explicitly chosen not to increase the governance level of the procurement team based on the risk a device poses. This would lead to high ranked procurement leaders that are detached from the actual working processes, while it is necessary to have a procurement leader that is knowledgeable about the risks and working processes.

The supervision team supervises the procurement team. The involvement of the supervision team depends on the risk coming with a medical device. The involvement can either be procedural, for which it is supervised if certain activities are carried out, or substantive, for which it is also supervised if the outcome of activities are correct. The composition of the procurement team depends on the required expertise for the supervision tasks. Procedural supervision will require knowledge about the procedures that are performed by the procurement team. Substantive supervision will require expertise about the
medical device and work environment as well. The governance level of the supervision team depends on the risk coming with a medical device. It is chosen to increase the governance level when the risk increases. This shifts the responsibility of the governance to greater empowerment levels and closer to the executive board, who in the end is responsible for the safety of patients and personnel.

The risk level during use, which is indicated in the framework above, is divided in four levels, from low to high. The current maximum of possibilities for a dimension for the procurement or the supervision team is four, so for simplicity reasons a total of four risk levels are defined. If in the future the number of values for a dimension changes, the risk levels should change accordingly.

The eight indicators found with sub-question 6 are used to determine the risk level. Each factor is measured in a certain unit, with a certain bandwidth of possible outcomes. This research provides this bandwidth per factor, but it is open for changes.

With the unit and bandwidth of each indicator it is possible to estimate a risk level. The risk level can be chosen on basis of the highest individual score of an indicator, or on the sum of the scores of the indicators. It is chosen to work with the sum of the scores for two reasons. The first reason is that the sum of the scores leads to less high-risk procurements, which is assumed to be not acceptable for the executive core. The second reason is that the gradual approach represents the causal diagram, in which all values influence the risk value, and not just one.

risk assessment form to calculate the risk score based on 8 indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Bandwidth</th>
<th>Score per indicator</th>
<th>Normalized score per indicator</th>
<th>Weight per indicator</th>
<th>Normalized weighted score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity of a device technology</td>
<td>introduction, growth, maturity, decline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CE risk class</td>
<td>L, II/a, IIIb or III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of departments</td>
<td>between 1 and 50, with the addition of the number of divisions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of treatments per department</td>
<td>rare, average, frequent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actions per treatment</td>
<td>low, medium, high</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience of user</td>
<td>low, medium, high</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time per treatment</td>
<td>seconds, minutes, hours, days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required number of trainings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Legend: blue = device properties ; green = usage characteristic ; purple = introduction property)

The risk assessment score provides the possibility to estimate each score of a specific medical device. In column 3 the value for each indicator is written down. In column 4 each score is normalized using the bandwidth. In column 6 the normalized scores are multiplied with the weights of column 5, providing the normalized weighted score per indicator. The sum of this column provides the risk score of a device.

The risk score of a device will fall in a bandwidth of possible outcomes. The bandwidth is divided in four risk levels, from low to high, as is indicated in the framework. The weights provide an opportunity to change the importance of one factor opposed to the others. The weights should be kept constant over the years so to it is possible to compare risk scores of medical devices. In the future it might be possible to change the weight values based on experience that some indicators are more important than others.
CHAPTER 11. RECOMMENDATIONS

The report has build up a framework that is recommended to the problem owner, the executive board. The recommendations are presented together with the limitations, and the assumptions that are used to form the advice. The problem definition (Chapter 1) that is used in this research is:

The executive board of the hospital wants to improve procurements, as at this moment procurements of medical devices are not compliant with the law and not effective in creating a safe environment during use. The advice to improve procurements must be acceptable for the executive core, as they are crucial for the successful use of the improvements.

Recommendations

1. It is recommended to implement the framework (developed in Chapter 9) for all procurement processes. With this framework the hospital will have a flexible allocation of experts in procurements. The framework advises the procurement leader on the establishment of a procurement team and supervision team, based on the possible risks for patients and personnel during use of a medical device. If the risk is low, there is no need to use the valuable time of experts in the procurement process. The framework will then advise not to involve experts. If the risk is high, the framework will advise to involve other experts. The involvement of experts is righteous if the risk is high. The involved experts provide a basis for the rest of the course of the procurement process to evade or mitigate risks that are introduced with the new medical device.

2. It is recommended to implement the framework (developed in Chapter 9) for all gifts to the hospital. At this moment medical devices that are given to the hospital are not part of the budgeting and the procurement process. This creates a situation in which the use of gifts is most likely based on the fact that it is free, and not on aspects such as safety, total cost of ownership or effectiveness of treatment. These gifts introduce a possible risk to patients and personnel. The framework is not based on the value of a medical device that is procured, so also for gifts it is possible to assess its potential risk level. With this risk level it can be decided if it is required to form a ‘procurement’ team to judge if it is possible to mitigate risks and if residual risks are acceptable.

Limitations of the framework

1. The framework is developed on a conceptual level. It provides a start for improving the procurement process. A more usable version needs to be developed before it can be implemented. The bandwidth and the weight of each risk indicator need to be determined before the total risk level can be used to determine the required procurement form. It is up to the hospital itself to create a usable version. The most capable persons to judge the bandwidth and weight of each risk indicator are the internal experts.

2. For the framework to be trusted, it is required to test it. These tests are not performed in this research. The nature of the problem makes it impossible to test the framework with mathematical models. Therefore the tests can only be performed in reality, with real procurements.
3. The framework provides an opportunity to improve procurements by the formation of a procurement team, involving experts and determining the form in which they work together. This provides a basis to improve the other activities in the procurement, such as the requirements specification, a risk analysis, the selection of suppliers and user tests. Hence, these other activities need to be researched and improved before a complete procurement method can be introduced and used by the executive board that complies with requirements for a quality management system, and increases the safety during use.

Assumptions

Several assumptions were made that were important for the framework. If an assumption is falsified this will require the framework to be adjusted.

1. It is assumed that the hospital under study has an organisational form that can be typed as a professional bureaucracy. This assumption includes that the executive board (*Raad van Bestuur*) is dependent on the executive core, the specialists, for their benevolence to share knowledge.

2. Non CE-certified medical devices are not part of this research. If these devices are taken in use, they must be judged by a commission on ethical, legal and safety aspects. It is assumed that this commission provides a good barrier to exclude devices that are unsafe to use.

3. It is assumed that the procurement process is the first possibility of a hospital to improve the safety of use of medical devices. An academic hospital is involved in the research and development, also for medical devices. The possibilities for the academic hospital to improve safety via activities in research and development is not researched.

4. The executive core and the facilitating departments are seen as experts on their own working terrain. The possibility to include external experts in the procurement is available in the framework. It is assumed that the executive core and the facilitating departments are capable of judging when themselves if they are knowledgeable enough to procure a medical device.

5. Is assumed that the higher the CE class is, the higher the chance that an adverse event is deadly. Although this might be true for the existing medical devices, it is very well possible that new medical devices are classified wrong. In such a case the framework makes a wrong risk estimation.

6. It is assumed that it is possible to estimate the indicators of the framework before the device is in use by the expert in the hospital.

7. In the causal diagram it is assumed that the more actions per treatment, the higher the chance on a failure of the interface between user and device. As a result the number of actions per treatment becomes indicative for the chance on adverse events. If this assumption is falsified, it is important to remove this criterion from the framework.
CHAPTER 12. FURTHER RESEARCH

During this exploratory research more research questions were raised than were actually solved. These questions come from throughout the report and are gathered in this chapter. The applied questions have their nature mostly from part 2 of this report. The more theoretical questions come from the discussions during this graduation project. There is a gradation in the questions, from more interesting for the LUMC to more interesting for the TU Delft.

What processes are required for the specification phase and the selection phase of the procurement in order to increase the safety of use of medical devices?

The research question above continues the work that is done in this research and focuses on the two steps after the formation of a procurement team; the specification of requirements and the selection of a producer. The framework that is used in this research to can also be used to create different process requirements in the following steps. The figure 7.1 already provides a nice start for this research, but more measures are most likely available. All these possible measures need to be judged on effectiveness and on which risk level they are appropriate to use. Once that is finished, it is possible to develop a protocol for the whole procurement phase that is aimed to decrease risks during use of medical devices.

How can the framework be introduced without loosing support of crucial knowledge actors?

If the framework is ready for introduction, an introduction strategy needs to be made. Hospitals are professional bureaucracies, in which the operational decision power is with the executive core. As defined by Mintzberg, it requires diplomacy to invoke changes in the working processes of the professional bureaucracy. This creates the interesting situation in which the executive board has to use diplomacy to create an acceptance basis for the framework.

This framework reduces the decision power of the staff, as they need to provide a good reason not to follow up the advice coming from the framework. Next to that the framework will most probably lead to an increasing amount of their time to be spent on procurements, time that is in direct competition with the time spent on healing patients, research and education of students.

This requires research on how to introduce this method into the hospital. It needs to be clear which trade-offs and balances between resources spent on procurements and on core processes are possible to propose to the executive core, without compensating the effectiveness of the framework.

What are the possibilities of device sharing, without loosing endangering patients?

During this research it was learned that a laser was shared between two departments. The request to share the laser came from one department that needed a laser, but could not afford it. The other departments only used the device only one or two days a week. With some luck, adaptations and research it was possible to use the laser on two departments.

This small example indicates that it is possible to share devices. The example was a complex one, as it was required to make some adaptations to the device in order to use it, but most probably there are even possibilities to share devices without changing anything. By one of the first healthcare entrepreneurs\textsuperscript{15} it was named as one of several essential opportunities to lower the costs.

\textsuperscript{15} Loek Winter in Buitenhof (VPRO) on 4 Oktober 2009
Sharing devices has the potential to lower the costs of the healthcare system. But sharing devices has its limits, as some devices are required to be available for stand-by for emergency situations, but also for the comfort of patients. Sharing thus has its limits. At this moment it is not known what are the possibilities of sharing devices. This on itself requires a vast enquiry amongst all departments of a hospital, as information is needed of the time a device is in use, how crucial and mobile that device is and what the wishes of new devices are. Then a whole database of devices that can be shared should be made, as well as a clear distribution of responsibilities for the shared devices.

Before starting such an operation, it is interesting to model this. A model that works on estimations of hospital experts for only a limited group of devices makes it possible to learn about the consequences of different levels of sharing devices for the curing outcomes of the hospital. This will provide input for the decision to start sharing devices in a hospital. This will provide a more solid ground for such a decision than the anecdotic claims that are made at this moment.

On what basis are budget allocation decisions made?
And on which information is it advisable to base the budget allocation?

In Chapter 3 it was found that the executive board based their budget allocation decisions for the investments above €100k on the strategic plan, a motivated request and advice of the management teams of the different divisions. And it was found that the budget allocation decisions of the procurements below €100k are made by the divisions themselves. The budget for these investments comes from lump sums that are granted to each department by the executive board based on historical trends. It remained unclear what information precisely is used in the budget allocations by the executive board, nor how that information is valued in the decision. Two clear symptoms of a possible problem were named in the interviews; the unfair allocation of lump sums between departments compared to their throughput, and that allocation decisions for investments above €100k are not motivated by the board.

Information on a national level about the methods or processes executive boards of hospitals go through was not found. So the basis of possible improvements of the budget allocation decisions is missing at this moment. This lack of information even makes it impossible to form a good problem definition. A possible problem could be that the current budget allocation process in hospitals leads to suboptimal results in curing possibilities and outcomes for the Dutch society. Or that at this moment it is not possible to judge executive boards on their achievements by the external parties as insurers and regulators. These two examples are only indicative examples. More research is required in order to make it possible to discover similarities and differences, so to discover general trends.

Connected to this is a new research discipline that is ‘entering’ hospitals, called mini-HTA. It is a derivative of a method called Health Technology Assessment (HTA), which is already in use with success on a national level for the regulation of healthcare technologies, in different countries like Sweden, Canada and the Netherlands\textsuperscript{16}. But the application of it on an institute level is not yet accomplished. As far as is known, this is the first method that is specifically developed for the healthcare sector to assess costs and benefits, including potential risks in the costs and benefits. It is not known if there are more methods. HTA will provide a good start in advising the executive boards of hospitals how its decision quality can be improved.

What are the long-term results of the measures that are being implemented at this moment and the near future in the Netherlands for two potentially conflicting goals; cutting costs and improving quality of healthcare?

Healthcare systems in almost all western nations face the same two problems; the costs of the healthcare systems increase each year, and the quality of healthcare is unacceptable for society. The latter problem is described in Chapter 1 and Appendix E. The former problem is described here.

In the Netherlands, the costs of the healthcare system are rising because of an ageing and growing population, and by increasing costs per treatment. In total these two factors has lead to an increase of healthcare costs of 50% between 1994 - 2003, a process that is not yet stopped. The increasing costs now become a reason to debate the healthcare system. This is visible in the publications in the media each time the standard insurance tariff is raised and the frequent debates between social and liberal parties in Dutch Parliament on the cost distributions of the insurance, and income of healthcare directors.

Especially the baby boom generation has profited from the growing welfare of the Western world, while at the same time the healthcare costs were rising. The younger generations encounter a stagnating growth of economies, while the costs of healthcare keep on rising. The Council for Public Health and Health Care (Raad voor de Volksgezondheid en Zorg) foresee that the rising costs of healthcare could become a treat to the solidarity of distribution of healthcare costs.

A regulated healthcare insurance market was introduced in 2006 in order to lower the costs. The key was that consumers will seek for the lowest annual costs for insurance, which creates competition for consumers. But it turned out not to work, as consumers are not interested to change insurer for the couple of Euros that could be saved. And the costs kept on rising.

In the future the healthcare providers will (possibly) also be allowed to make profit. The results of such a change of the healthcare market are not known. A possibility is that it leads to a less equal treatment of patients. Already a hospital offered the possibility to surpass a waiting list by paying a certain fee. And one can think of far worse possibilities to earn profit by discriminating between patients.

Besides a violation of the equality principle of healthcare provision, there also is the possibility that the quality of healthcare provision is violated in the competition between healthcare providers. This would create a true dilemma for the Ministry of Health, as that is conflicting with the other goal, that of quality improvement. The current results of the policies aimed at increasing quality and at decreasing costs have the potential to be conflicting. The long-term effects of these policies apart are not published in literature, and neither is the effect of these two policies combined.

As is mentioned above, other nations face the same problems, but have implemented or are developing other policies. This is inherent by the differences there are present in the healthcare sectors between the nations, as well as cultural and political differences. The differences in the policies will lead to different long-term outcomes. For researchers this provides a possibility to compare policies between nations, and to model and forecast the long-term effects of these policies in the Dutch healthcare system. That is a true policy analysis study. It provides answers to which policies are robust and which are not, which policies strengthen the dilemma between increasing quality and reducing costs and which do not. For the Ministry of Health this research provides the opportunity to reflect its policies and to implement changes were required.

CHAPTER 13. RESEARCH REFLECTION

In this chapter it is indicated what is learned from this graduation. These points are presented here in the form of recommendations if in the future a similar research is undertaken.

1. A research proposal is the basis for the rest of the research. It explains what, what not, why and how the research is carried out, and it contains a planning when what is done. The research proposal for the graduation project was written for a somewhat different field of research in the healthcare sector, when I decided to change course and start this research project. The research proposal was judged to be of sufficient content to also support this research project. During the research it was found that frequently the research questions were changing, something seen by me as direct result of the mismatch between what was studied and what was in the research proposal. Of course there will always be changes of research questions, but in this research there were too many changes.

A research is an adaptive project, especially this research, as the exact problem was not known at the beginning because the problem definition was wide and could not be specified narrower. So the straightforward recommendation that in the future an applicable research proposal should be used will encounter the effect that during the course of research the problem tends to shift. So besides the presence of an applied proposal, I recommend a reflection moment after each answer to a sub-question or finishing an important process. Then it should be explained what the work that is finished contributes and how it could alter the research planning.

In short, a more aware style of researching, from the beginning on, is something that would have helped increased the effectiveness and efficiency. The course ‘time management’ followed at the end of September already contributed to an improvement.

2. The interviews were started shortly after joining the working group. So there was a limited amount of time to prepare the interviews. It was chosen to use a loose line of questioning, as to leave room for interesting facts and findings. This is a good approach for qualitative interviews. The short preparation time and the loos questionnaire complicated the presentation of data and the analysis in the report, as there was no structured approach or framework developed. As a result it took more time than was actually planned. At the end there was the gut feeling that more could have discovered during the interviews only if the preparation was more thorough. But possibly that is a feeling that is always present at the end of interviews, caused by the simple fact that in the first interview there is a lower understanding of the system than in the last interview. Hence, in the last interview the questions are likely to be more to the point and useful.

The recommendation is to develop a structure of how the interviews are going to be presented and analysed before one starts the interviews. With that approach it is still possible to use a loose questionnaire, but it does provide the interviewer with more clear guidelines in the interview, without loosing the possibility of exploring issues during the interviews that were not foreseen.
3. This research explored a completely unstudied field, that of procurements in hospitals. This field was not researched before, and the problems in this field are at this moment solved by the people working in the field. The interviews did contribute a lot of information on how the current situation is, but it provided mere anecdotic recommendations on how to improve the future. As this is such a unstudied field, the people working in the field know best what to improve and how to improve. It is recommended, when in the future another unstudied field is researched, to involve the people working in the field in the design of an advice. That would provide the hospital with a more applied framework than is developed in this research, which is something that is required for the problem owner. The framework in this report is still on a conceptual level.

4. A last recommendation is to learn to let go nuances that are seen by me as important, but only clutter the essence for others. The skill to look at a problem from many different angles at once might be a great analytical skill, but it is required for perspicuous communication to first present the essence repeatedly, before naming nuances.
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Resource list

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Laws & Norms

Kwaliteitswet Zorginstellingen Quality Law Healthcare Providers
Wet op de Medische Hulpmiddelen Law on the Medical Appliances
Besluit Medische Hulpmiddelen Decree Medical Appliances
Besluit In-Vitro Diagnostica Decree In-Vitro Diagnostics
Besluit Actieve Implantaten Decree Active Implants
Regeling Classificatie Medische Hulpmiddelen Regulation Classification on Medical Appliances

Interviews

19 interviews in the LUMC, in the period April - May

Ms. W. Oortwijn19 (ECORYS, Health Technology Assessment expert), 27 February 2009
Topic: national and organisation methods to decide to adopt or exclude a new medical technology,

Mr. M. Besters (Rathenau Instituut, department Technology Assessment), 4 April 2009
Topic: Future use of medical technology in and connected to hospitals

Ms. M. den Breejen (Ministry of Health, Welfare and Sport, department market approval and safe use of medical products), 4 February 2009
Topic: Regulation for medical devices to enter the Dutch market

Class

Safety classes for Clinical Physicists at the Eindhoven University of Technology,
18 and 25 March, 1 and 8 April (2009)

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§ A.2 Explanation of a goal tree

It is important to know how to read this goal tree. The goals are visualized with a blue and red rectangles. The red goals are high-level goals that represent the reason why the organisation exists. The blue goals are supportive to the high goals and are more prone to changes from internal and external influences. The means to achieve a goal are visualized with green clouds. The green clouds are directly located underneath the goal(s) it supports.

The top red block represents the highest goal the LUMC has. The three red goals below that are supportive to this goal. The hierarchy is from top (high level) to bottom (low level) and is visualized with the black lines. The three high level goals are supported by the blue lower level goals. These goals are called low level goals here, as it is possible to directly attach a means to it. Not all means have quantified target, as some cannot be quantified and some are not quantified in the LUMC documents.

§ A.3 Argumentation of the goal tree

Here it will be explained how the mission statement (LUMC, 2009c) and the strategic paper 2009 – 2013 (LUMC, 2009d) are translated into this goal tree. The rectangles and clouds are numbered on their top left side. Their origin is explained here below per numbered item.

1. From the mission statement, under heading ‘Mission Statement’, 1st paragraph: “Het Leids Universitair Medisch Centrum (LUMC) streeft naar een (inter)nationaal erkende vooraanstaande rol in de verbetering van de kwaliteit van de gezondheidszorg."
2. From the mission statement, under heading ‘Beter zijn Beter worden’, 1st alinea: “Het Leids Universitair Medisch Centrum stelt zich tot doel om zijn kerntaken op het hoogst mogelijke niveau uit te voeren. Het LUMC streeft er dan ook naar de hoogste kwaliteit te bieden, …” The core business of the LUMC are named under the heading ‘Kerntaken’ and are patient care, research and education (graduates and post-graduates).

From the strategy plan, page 6 target 1: “De zorg in het LUMC kenmerkt zich door vernieuwing, kwaliteit en samenhang. Het LUMC excelleert en groeit in de publieke zorgtaken van UMC’s”

All this is translated into blocks 2, 3 and 4.

3. See point 2
4. See point 2
5. This lower level goal is extracted out of the strategy plan. Point 14 is a means that directly supports this goal.
6. This lower level goal is extracted out of the strategy plan. Points 15 and 16 are means that directly supports this goal.

Point 15 is a clear target that supports the goal to improve the attractiveness of the education. Point 16 aims at staying the largest postgraduate research centre. So it is wanted to stay attractive

7. This lower level goal is extracted out of points 17, 18 and 19. All three means directly support the goal to increase the attractiveness of the education of the LUMC

Point 17 is aimed at improving the quantity of researchers, which in the end can lead to a higher quality. It is not a direct causal link, but nevertheless it is mentioned under the goal of point 7.

Point 18 can support two goals, 1) reduce pressure of education program on LUMC and 2) Increase education level of students. Both are valid here. It is chosen to use goal 2, as this also connects to measures mentioned under point 18 and 19. Furthermore is it assumed that the goal is not 1), as this would mean the LUMC is denying its legitimacy as an academic hospital.

Point 19

8. From the mission statement under heading ‘Beter zijn Beter worden’, 1st alinea: Het LUMC streeft er dan ook naar de hoogste kwaliteit te bieden, zowel in medisch technisch opzicht, als in de zorg en aandacht voor de patiënt.” This is split up in blocks 8 and 9.

9. See point 8
10. From the mission statement, under heading ‘Beter zijn Beter worden’ 2nd alinea: “De interactie van fundamenteel onderzoek en patiëntenzorg vormt de basis van het beleid.” This is a clear emphasis that the research should lead to clinical improvements. That is translated into block 10. This goal supports both high level goals for patient care and research.

11. This goal is indirectly extracted from measures 23 and 24. It is closely related to prestige, but is something that is distinct here as the outcome can be very different.

12. This goal is indirectly extracted from measures 24, 25 and 26. Prestige here is not a negative word. The goal only describes the goal to show more visibly the achievements of the LUMC.

13. From the strategy plan, page 14, 1st alinea: “dat wetenschapsbeoefening niet kan zonder het onderhouden van netwerken. Het gaat zowel om inspireren als om samenwerking die zicht niet tot Nederland beperkt.” This clearly indicates the goal of increasing ones networks in order to improve the research quality.

14. From the strategy plan, page 6, target 7: “De gemeten satisfactie van studenten over de studie ligt
gemiddeld boven 7.5, ...

15. From the strategy plan, page 6, target 8: “De Leidse OOR behoort tot de aantrekkelijkste clusters voor de opleiding tot specialist.”

16. From the strategy plan, page 6, target 10: “De Boerhaave cursussen hebben hun positie als Nederlandse nascholingsorganisatie met de meeste cursisten versterkt.”

17. From the strategy plan, page 6, target 7: “… het aantal studenten dat kiest voor een wetenschappelijke carrière behoort tot het hoogste van Nederland.”


19. From the strategy plan, page 6, target 7: “… 20 procent van de studenten participeert in extracurriculaire activiteiten voor excel lente studenten …”

20. From the strategy plan, page 6, target 7: “Zorglogistiek, onderwijs en onderzoek worden verbetd door een nieuwe generatie Elctronisch Patiënten Dossier/Ziekenhuis Informatiesysteem.” This is not only related to the higher goal of higher quality of specialized care, but also to the higher goals of education and research. It is believed that the primary reason for this introduction is the improvement of patient safety, and so to the quality of the care. This does have effects on education and research goals. However, it is believed that that is not the main goal of the introduction of these systems. This believe is based on the fact that these kind of systems are more and more needed to manage all devices in the hospital and the fact that these management systems are (implicitly) obligated by the Quality Law for all hospitals, also the one who do not deliver education and research.

21. From the strategy plan, page 6, target 3: “De kwaliteit en veiligheid van patiëntenzorg is aantoonbaar verbeterd…” Patient care will be improved by introducing the NIAZ quality norms in every process in the hospital (page 13).

22. From the strategy plan, page 6, target 3: “… meer dan de helft van de patiëntenzorg is ondergebracht in zorgpaden.”

23. From the strategy plan, page 6, target 4: “Keuzes van wetenschappelijk activiteiten en keuzes voor investeringen in wetenschappelijke infrastructuur sluiten aan bij klinische profilering.”

24. From the strategy plan, page 6, target 6: “De betrokkenheid van LUMC-medewerkers bij knelpunten in de publieke gezondheidszorg is duidelijk zichtbaar.”

25. From the strategy plan, page 6, target 5: Hey LUMC hoort bij de topcentra voor medische vernieuwing en medisch onderzoek gemeten zowel via bibliometrische indices, toegevoegde sociale waarde en parameters van valorisatie.

From the mission statement, under heading ‘Beter zijn Beter worden’, 3rd alinea: “Voor wat betreft het onderzoek wil het LUMC tot de internationale top blijven behoren.”

26. From the strategy plan, page 16, under heading ‘kennisvalorisatie’, 1st alinea: “In sommige gevallen is voor de vertaling van de in het LUMC aanwezige kennis en kunde naar maatschappelijke toepassing een commercieel traject de aangewezen weg naar toepassing in de patiëntenzorg. Vaak zal dit gaan om samenwerking met industriële partners in de ontwikkeling van nieuwe producten.”

27. From the strategy plan, page 6, target 9: “… ten minste 25 procent van de studenten en onderzoekers komt uit het buitenland of gaat naar het buitenland.”
Part of the directorates (located under ‘Raad van Bestuur’ are ICT, facilitating services (see figure B.3) and employees supporting the board.
Appendix B

Organisation charts of LUMC

Figure B.3: Organisation chart of the facilitating services
APPENDIX C. ORGANISATIONAL REVIEW OF LUMC

In the book *Structures in fives: designing effective organisations*, Mintzberg repeatedly uses hospitals and education centres as the classic examples of organisations he refers to as a professional bureaucracy. In general most service industries with complex but similar problems are organized as professional bureaucracies.

§ C.1 Comparison of properties of professional bureaucracy with organisation LUMC.

As the LUMC is both a hospital and an educational centre, it is argued that if the LUMC shares the main properties (indicated by o) Mintzberg states for a professional bureaucracy. The main properties are (Mintzberg, 1992):

- **Primary coordination mechanism of work is by standardization of skills**
  - This is true for nurses and doctors in the hospital. They are trained for a long time by classes and by their future colleagues and receive additional training and education whenever they specialize themselves. The training is standardized by law, but more importantly via the professional groups. These groups also facilitate the exchange of experiences between hospitals.

- **The most important part of the organisation is the executive core**
  - The doctors and nurses within the hospital deliver the actual care. All other things are subordinate to their process. Relative to other organisational forms, this results in a large executive core and smaller middle and top management and techno structure (process planners). The services that make the core business possible are necessary and thus are as large as is needed.

- **The design of the organization is characterized by horizontal and vertical decentralization, as well as horizontal specialisation and training**
  - The organisational chart in Appendix B clearly shows a very flat structure. The executive core has a knowledge monopoly and thus will decide how to handle processes of the core business of the hospital, healing patients. As there are different specialties, this creates all different blocks of knowledge monopolies working next to another. These small groups, especially within the LUMC, strive to increase their knowledge and experience.

- **The situational factors of importance are: complex but stable environment, not a high technology sector, subject to trends and little regulation**
  - Every patient is unique, but every patient can only have a certain amount of complication. Because of the separation of expertise of the whole human body in many small departments, these departments experience a limited amount of diversity in complications. It is still complex due to the many interactions within the human body and the small differences in properties between humans. A hospital no longer can be called a low technology environment. Mintzberg argues that specialists will try to exclude technology as long as possible, as this makes them dependent on others (technicians and engineers). This is not believed to be true for the LUMC, as technology can contribute a lot for new curing possibilities.

Now the four main characteristics of a professional bureaucracy are reflected to that of a hospital, it is clear that a hospital like the LUMC has an organization similar to that of a professional bureaucracy.
§ C.2 Problems with governing a professional bureaucracy

As we can assume that a hospital has an organisation comparable to a professional bureaucracy, a summary of possible problems with this organisational structure is summed up here in order get insight in the research problem from an organisational perspective (Mintzberg, 1992):

1. Multi-issue problems require coordination that is not present: Because all experts in the organisation all have different areas of expertise, there is no one looking at the complete picture. This creates problems of coordination between experts. Anything that requires input of multiple experts requires a strong communication between these experts. But experts are used to work on their own and have the complete authority on their problem area.

2. Experts are hard to control: Experts have the knowledge monopoly on their area of expertise. This leads to an organisation that finds it hard to discover misbehaving experts, as no expert or manager can judge another expert. This can and will lead to experts that repeat their solution on any type of problem, experts that do not train themselves as much as is needed and experts that think and act as if they are more important than the organisation.

3. Multi-disciplinary innovations are hard to accomplish: Innovations are hard to establish if they involve more than one area of expertise. The expert that will try to establish a new area of expertise with multi disciplines will have to work hard not to be pushed into one of the disciplines by the organisation. This reaction on new expertise areas results in a lack of innovation into the new and unknown problems in the world.

One core problem lies at the bottom of points 1 to 3. The expertise of employees working on the core business leads to authority and autonomy at the bottom of the organisation. As the middle and top management cannot measure the output parameters as the work is too complex, it is impossible for the management to coordinate and control the organisation directly. Still this organisational structure with authority and autonomy at the bottom is required to solve the complex problems adequately. So how to solve problems that exceed the individual expertise areas, like the management of all devices in a hospital?

§ C.3 Possibilities to overcome institute wide governance problems

The one think Mintzberg sees as an effective method to coordinate such problems by the management (for this research that is the executive board of the LUMC) is to use diplomacy to persuade the expert to change their behaviour, the training requirements and professional standards, thus to change the standard of skills of experts.

Another method to change the output of a professional bureaucracy, especially for society, is to address the experts on their lack of fulfilment of their responsibilities. This is best done via the representative professional groups and not directly addressed to the experts.

Other coordination methods Mintzberg identifies will be less effective. Standardization of work process is hard, as the work is too complex. Standardization of output is also hard in most cases, as the output is hard to measure. Who determines if the health status the patient leaves the hospital with is indeed the best that could have been done? Direct supervision will only work for the extreme deviations, as the supervisor is not knowledgeable enough. All three coordination methods will probably demotivate the expert, as he no longer has the freedom to do his work as he wants. Furthermore will it disturb the relation between expert and client, leading to a less effective work output.
APPENDIX D. CLASSIFICATION OF MEDICAL APPLIANCES

The Law on medical appliances (Wet op de medische hulpmiddelen) states what is illegal in the Netherlands and what measures the Minister of health is allowed to take regarding medical appliances. Basically it is illegal not to comply with the Decree medical appliances (Besluit medische hulpmiddelen). This Decree refers to the Decree in-vitro diagnostics (Besluit in-vitro diagnostica) and the Decree active implants (Besluit actieve implantaten). The Decree medical appliances describe with what regulation a producer should comply in order to legally market a medical appliance. The decrees for in-vitro diagnostics and for active implants describe specific regulation for these two kinds of medical appliances. The classification of medical appliances in risk categories is elaborated in the Regulation for classification medical appliances (Regeling classificatie medische hulpmiddelen).

As of 21 March 2010, the three decrees and the regulation scheme will not contain references to appendices of the Decrees and regulation, but to the European regulation from which they stem from.

In this appendix, the definitions used in the regulation are summed up (§ D.1).

From the list of definitions, a definition of ‘medical device’ is chosen that fits the meaning the LUMC has for ‘medical device’ (§ D.2). With the colouring of the definitions it is indicated if the definition is included or excluded.

§ D.1 Definitions

The definitions are numbered from 1 to 10 in bold script. Without further notice, all definitions are from article 1 of the designated law, decree or regulation, if it is not stated differently. The abbreviations are:

- Law on medical appliances L-MA
- Decree medical appliances D-MA
- Decree active implants D-AI
- Regulation for classification medical appliances R-MA
- Decree in-vitro diagnostics D-IVD

1. Medical appliance (L-MA)

Any instrument, apparatus or device, any substance or other article, alone or in combination, including the required software for its proper functioning, and that it is intended by the producer to be used with humans for the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,
- Investigation, replacement or modification of the anatomy or a physiological process,
- Control of conception,

For which principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but such appliances can support this.

2. The definition of medical appliance is not valid for (summary of D-MA article 3)

1. In-vitro diagnostics if is covered by the relevant decree
2. Active implants if it is covered by the relevant decree
3. Medical appliances meant to administer medicine, only if:
Appendix D  Classification of medical appliances

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3. Custom sized medical appliance (D-MA)
A medical appliance that is purposely crafted according to prescriptions of a doctor or another person that is authorized in name of its profession, under which his responsibility the specific properties of the design are indicated and that has the purpose to be used on a certain patient

4. Medical Appliance intended for clinical research (D-MA)
A medical appliance that is intended to be used by a doctor or another person that is authorized in name of its profession, with the purpose to be applied in proper clinical environment for research as is indicated in article 13, number 5, designated ministerial regulation applicable for the clinical evaluation.

5. Active medical appliance (R-MA, D-AI)
A medical appliance, including the accessories and software needed for the proper functioning, that for its functioning depends on an electric energy source or any other source not directly coming from energy sources made by the human body or gravitation

5a. Active therapeutic medical appliance (R-MA)
An active medical appliance, used alone or in combination with another medical appliance, and is meant to support, change, or restore biological functions or structures as part of a treatment or relief of an illness, trauma or handicap.

5b. Active medical appliance for diagnosis (R-MA)
An active medical appliance, used alone or in combination with another medical appliance, and is meant to deliver information on the detection, diagnosis, control of a treatment of physiological systems, health status or a congenital defect.

6. Reusable surgical medical appliance (R-MA)
A medical appliance, not connected to an active medical appliance, meant to be used in a surgical procedure, like cut, bore, saw, scrape, clasp, contract, stitch up, or comparable acts, which can be used again after the proper treatments.

7. Invasive medical appliance with surgical nature (R-MA)
A medical appliance that enter in the human body through the body surface in or as a result of a surgical procedure, as well as an appliance that permanently enters the human body via other permanent body openings.

8. Invasive medical appliance (R-MA)
A medical appliance that partly or whole enters in the human body, through a body opening or through the body surface

9. Implantable medical appliance (R-MA)
A medical appliance that is designed to:
   a. completely enter the human body, or
   b. replace an epithelium surface or the surface of the eye, by means of a surgical procedure and which is meant to be in place after the surgical procedure.

10. Active implant (D-AI)
An active medical appliance that is designed to, partially or fully, be placed in the human body using surgical or medical manners or body opening, and is designated to stay in the human body after that procedure

10a. Custom sized active implant (D-AI)
An active implant that specifically is crafted according to prescription of the medical specialist, under which his responsibility the specific properties of the design are indicated and that has the purpose to be used on a certain patient

10b. Active implant intended for clinical research (D-AI)
An active implant that is intended to be used by a medical specialist, with the purpose to be applied in proper clinical environment for research.

11. In-vitro diagnosticum (D-IVD)
A medical appliance that uses an agent, a reactive material, a calibration material, a control material, a kit, an instrument, a device an aid or a system, that on its own or combined is used and is intended by the producer to perform in-vitro diagnoses of specimen of human origin, including donor blood and tissue, with the purpose to provide information about:
   • physiological or pathological conditions, or
   • a heredity malfunction
   • to determine the safety and unite chanc
   • to determine the effects of therapeutic measures

11a. High-risk diagnostic (D-IVD)
An in-vitro diagnostic meant primarily or mainly for
   • The detection, confirmation and quantification of the presence of human specimen of markers with HIV, HTLV I and II, hepatitis B, C and D
   • The detection of tumour marking substances
11b. In-vitro diagnostic meant for effectiveness studies (D-IVD)
An in-vitro diagnostic that by the producer is meant to be tested once or more on its effectiveness in medical laboratories or another suitable place, outside its own company space.

11c. New type of in-vitro diagnostic (D-IVD)
A type of in-vitro diagnostic:
- That concerning the material under investigation or another parameter, distinct itself from other types that are marketed the last three years in one of the member states.
- That for its application uses an analysis technology that the last three years was not permanently used for the investigation of a material or another parameter.

11d. In-vitro diagnostics meant for self testing (D-IVD)
An in-vitro diagnostic by the producer intended for self-testing by amateurs in a home situation.

12. Control and calibration material (D-IVD)
A substance, material or article, designed by the producer to indicate a measure relation, or to indicate performance measures, of an in-vitro diagnostic in relation to its purpose.

13. Aiding appliance (D-MA, D-IVD)
An appliance that is not a medical appliance, but is meant by the producer to be used together with a medical appliance, in order for the proper function of the medical appliance.

13a. Recipient of specimen (D-IVD)
A medical appliance, a vacuum type or not, that is specifically intended by the producer to collect and store specimen coming directly from the human body that are intended for in-vitro diagnostics.

§ D.2 Discussion
This part will discuss if a definition can be seen as a part of the definition of a medical device and is within the research boundaries. Below follows the confrontation of the definitions from law with this research.

The definition of medical appliance (number 1) is a very wide term. It includes appliances you would expect, such as diagnostic equipment, surgical devices, hospital beds, disposable and sterile goods and injection pumps. But it also contains the electronic patient file systems. The definition has no clear border in case a doctor looks at an MRI photo on his own computer and not the computer that comes with the MRI scanner. Strictly taken the doctor would not be allowed to make a diagnosis when it comes from his computer screen, as the screen and computer is probably not intended to be used as a medical appliance.

Of course what is not seen as a medical appliance (number 2) is valid here as well, with the exclusion of points 1 (in-vitro diagnostics) and 2 (active implants), as that are medical appliances.
A custom sized medical appliance (number 3) is an interesting definition. It is something purchased by the hospital, and it is seen as a medical appliance. But if one reads the rest of the decree, it is never a CE certified product, as part of the product is customized for every other patient. Only the parts that are not customized can be certified. Furthermore, as it is customized, it is probably meant for one patient and not bought on a large scale. The research boundaries excluded non-certified devices, so this is excluded as well. On important note: it does not exclude devices that are customized by the medical specialist himself. For example, pacemakers can be customized by the cardiologist but are not seen as custom sized medical appliances, but as active medical implant (number 9 or 10).

For a medical appliance intended for clinical research (number 4) again the same argumentation as for a custom sized medical appliance; it cannot be CE certified, and thus is it excluded from this research. One important note here is that clinical research by law requires a solid argumentation on necessity, safety and ethics before it can be started. This is more stringent than a purchase is required to be by law.

Without too much explanation is an active medical device (number 5, 5a and 5b) seen as what the LUMC sees as a medical device. It is electric, is used for treatment or diagnosis and will likely receive maintenance.

Reusable surgical medical appliances (number 6) are in nature passive appliances, as the medical staff operates them. Still they are medical and are devices, so they are considered in this research.

Any medical device that is implantable (number 9 and 10) will be included in this research. This is assumed, as this is a category of devices that could pose a great threat on patient safety as it is placed inside the human body. This therefore is also an important item to be included when improving the procurement process for medical devices.

Custom sized active implants (10a) and active implants (10b) intended for clinical research are not included in this research, as they cannot be CE certified. For custom sized implants the medical specialist will always tailor make the appliance. It is therefore not ordered in large quantities (less risk) and will be placed by the specialist himself (as he is responsible) on one patient at a time. It is assumed this secures the safety of patients to a reasonable level. For research with active implants (10b) the safety is secured by the stringent requirements by the law for a clinical research.

In-vitro diagnostics of any kind (11, 11a, 11b, 11c, 11d) are part of this research. In-vitro diagnostics do not have a direct connection with the patient, but as it provides a diagnosis it is just as important for the patient as any other diagnostic device. Therefore, they are included.

Control and calibration material (12) do not have a relation with the patient, other than controlling and calibrating in-vitro diagnostics. If all control and calibration material would be seen as part of this research, too much is included to come to a workable research boundary. Therefore this will be excluded.

Aiding appliances (13), including recipients of specimen (13a), are seen as part of the definition of medical device, as they are required for the proper functioning of a medical device. It is not explicitly mentioned here, but also software that works with the medical device is seen as part of the aiding appliances, and thus as part of the definition of medical device.
APPENDIX E. GOVERNMENTAL ACTIONS AND REGULATIONS FOR QUALITY OF MEDICAL DEVICES IN THE HEALTHCARE SECTOR

This appendix will describe which regulation, norms and initiatives coming from the authorities are at this moment existent in the Netherlands and are of influence on hospital quality management systems in general and the procurement medical devices specific. It is not specifically related to one of the chapters in this report, but more a contextual important factor that is not relevant enough to be put in a chapter, but too important to be left out of the report.

§ E.1 chronologically describes the momentum generated by the quantification of the term patient safety. It lead to a mind change in hospitals (and most important, in the minds of specialists) that they could do better then they are doing at the moment. § E.2 summarizes the relevant regulation that exists for the offering and using medical appliances.

§ E.1 Patient safety as a driving force behind governmental actions

From specific demands to general requirements for hospitals with the Quality Law

Before 1996 the Dutch Ministry of Health would acknowledge which providers of healthcare could make use of financing from the Health Funding Law (Ziekenfondswet) and the General Law for Special Healthcare funding (Algemene Wet Bijzondere Ziektekosten), based on very specific conditions for all kinds of procedures. Because the conditions to be recognized were too specific on how a healthcare provider should operate, the recognition system did not work (MinVWS, 1997). In principal this would mean all hospitals had to be closed.

In 1996, the Quality Law for Healthcare Providers (Kwaliteitswet Zorginstellingen) replaced the recognition system by a system that prescribed what should be organized, instead of how it should be organized. Healthcare providers could now organize with their own vision how they would meet the prescribed quality norms. The Quality Law demands that healthcare providers deliver justifiable services, conduct a conscious quality policy, use a quality management system and make yearly quality reports for internal use. Furthermore should they improve their quality and the quality management system by making changes that are based on measured outcomes.

The Ministry of Health wants the representative groups of the specific types of healthcare providers to define and elaborate the term justifiable services and conscious quality policy explicitly, together with health insurers and patient organisations. Furthermore should they design and implement their own quality systems. Thus, the Quality Law demands self-regulation of the healthcare providers in order to come to a high quality health care system.

The supervision of healthcare providers is carried out by the Netherlands Healthcare Inspectorate (Inspectie van de Gezondheidszorg, from now on referred to as the Inspectorate). The Inspectorate supervises based on the reports of the representative groups. Furthermore the Inspectorate steers developments based upon its own experience and international trends.

So from 1996 on the Quality Law demands from hospitals to build, control, measure and improve their own quality management systems.
An unsafe healthcare system in the Netherlands

In 2000, with the report To Err is Human, the Institute of Medicine argued that hospitals in the U.S.A. can be more safe for patients to be treated in, as there are a large number of preventable adverse events. And hospitals should put real effort in preventing it, as the direct measurable loss of human lives, damage to human’s physical and emotional health and resulting economical costs are unacceptable to the standards to be expected from healthcare in the American society. The report was able to make a lasting impact by making patient safety one of the most important problems for not only hospitals (cure) but the whole healthcare sector, and opened the eyes of all involved in healthcare; policy makers, analysts, healthcare scholars, managers, doctors, nurses and of course patients.

This report primarily focused on the U.S.A., with the research statistics coming from American hospitals, the research carried out by an American organisation and recommendations primarily addressed to the American Congress (IOM, 2000). Nevertheless it was taken serious in the Netherlands by the government and the Inspectorate. The Inspectorate recognizes the seriousness of preventable adverse events, as the American numbers extrapolated to the Netherlands would mean that the dead of between 1500 and 6000 people could have been avoided, much more than from traffic accidents (IGZ, 2000 - p 9-11). They conclude that a complete reorientation on their main focus points and the high-risk areas in healthcare is necessary, together with a study of the impact of adverse events in the Netherlands.

The study of the impact of adverse events was done by NIVEL and EMGO institute and published in 2007. A quantitative study was done into the number of adverse events and preventable adverse events based on patient files of hospitals spread over the whole of the Netherlands. It is concluded that in the Netherlands 5.7% (± 0.6%, 95% Confidence Interval) of all hospitalized patients experience an adverse event. Of these adverse events, about 40% could have been prevented, that is 2.3% (± 0.4%, 95% CI) of the all hospitalized patients. In numbers that would mean that of a total of 1.3 million hospitalized patients, about 76,000 patients experienced adverse events, of which about 30,000 events could have been avoided (Wagner & de Bruijne, 2007).

Of all hospitalized persons, about 3% has died in the hospital. Of the patients who passed away, 10.7% (± 1.0%, 95% CI) suffered an adverse event. Of the died patients, between 4.1% (± 0.7%, 95% CI) passed away prematurely and can be related to preventable adverse event during treatment. In numbers that would mean that of about 42,000 died patients, about 4,500 experienced an adverse event and about 1,735 experienced a preventable adverse event (Wagner & de Bruijne, 2007).

A follow up research by Wagner et al. was published in 2008. This research was carried out on 50 departments from 21 hospitals on three department types: internal medicine, surgery and the emergency department. The department staff was asked to report anything that did not go as it supposed to go, related to patients. This includes near adverse events, adverse events and preventable adverse events. In total 8 categories of incidents were defined. The category directly related to medical devices is ‘material and devices’. This category ended up as the dominant category related to (near) incidents for the departments emergency and surgery, with 20.3% respectively 15.6%. On internal medicine less devices are used. As a result, (near) incidents related to material and devices were 5th, with 8.5%. The most dominant category for surgery and internal medicine is medication, with 33.0% respectively 41.9%. On the emergency department the dominant category was the cooperation between departments (24.5%), as it is a department that depends on others for expertise (Wagner, et al., 2008).
Actions to improve the use of a quality system in hospitals

The Ministry of Health and the Inspectorate did not expect the healthcare providers to comply to the Quality law for Healthcare providers immediately. In the Status of Healthcare 2002 (Staat van de Gezondheidszorg 2002) from the Inspectorate based on a study of NIVEL in 2000, it is concluded that only 5% of all care providers do actually have an integral quality management system (IGZ, 2002b). They conclude that self-regulation of hospitals has not worked in creating integral quality management system within an acceptable time frame.

The outcome of To Err is Human was the reason for the Minister of Health (Ministerie van Volksgezondheid, Welzijn en Sport) to start several quality improvement programs for the different branches of healthcare (MinVWS, 2009). The program created for the hospital branch is called Sneller Beter (Sooner Better), and was carried out together with The Dutch Organization of Hospitals (Nederlandse Vereniging van Ziekenhuizen – NVZ), The Order of Medical Specialists (Orde van Medisch Specialisten – OMS) and Nursing & Caring staff Netherlands (Verpleegkundigen & Verzorgenden Nederland – V&VN). Sneller Beter consisted out of three pillars with different goals. The first pillar was a review on quality, efficiency and effectiveness of the current practices in hospitals by external professionals from different industries. The second pillar aimed at improving transparency and comparability of hospitals with another. The third and last pillar aims to prove that quality improvements are possible, by a pilot implementation of the Sneller Beter concept in several Dutch hospitals (Consortium Sneller Beter Pijler 3, 2008).

An outcome of the first pillar is the report Hier werk je veilig, of je werkt hier niet, (You will work safe here, or you do not work here at all) of Rein Willems, then CEO of Shell Netherlands. It concluded that if the number of preventable adverse events would be reduced by 75% within 15 years, not only would it save a lot of lives, it would also reduce costs by an estimated €1–3 billion (based on To Err is Human). Four recommendations are given to reduce preventable adverse events (Willems, 2004):

1. All hospitals should work with a certified safety management system by 2008, supported by a cultural change that people can and do make mistakes
2. Hospital Boards should in the end responsible for safety in the hospital and must have the power to manage the organisation on safety and quality
3. Safety and quality should become a selection criterion of health insurers in order to increase them both, next to criteria as price and production
4. The government should act decisive and responsible on facilitating and checking the safety management systems of hospitals and let hospitals profit of a good system

Increasing concern about the use of medical devices in hospitals

The Inspectorate published four reports that gave attention to medical devices and medical appliances, in 2002, 2004, 2005 and 2008. These reports are summarized and discussed below.

The first report was published in 2002. The report was dedicated to one subject of the quality management system; medical devices. From an inquiry filled in by 103 Dutch hospitals, the Inspectorate summarized eight main concerns about the whole life-cycle of medical devices in relation with the quality system in Dutch hospitals (IGZ, 2002a) that needed to be improved by the hospital boards:
1. A managed and guaranteed quality management system is missing, most is undefined and not documented.
2. Risk management is not carried out and no risk control measures are taken.
3. Responsibilities for all tasks, except maintenance, are unclear defined.
4. Acceptation procedures (after a purchase) are present in only half the hospitals. Release procedures (after maintenance) are only present in a few hospitals.
5. The introduction processes on the departments are not guaranteed or obligated in all hospitals.
6. The administrative management system is not in all hospitals complete on all aspects.
7. More than half of the hospitals have arrear preventive maintenance.
8. Storage locations for devices are not sufficient in size, as hospital buildings were not build with in mind a fast growing amount of medical devices.

Points 4 and 5 are of importance for a purchase and introduction of a safe medical device. Points 1, 2 and 3 are indirectly important for the purchase of a safe device, and are of direct influence on the quality of the procurement itself. Point 8 is directly related to the infrastructure of the hospital and can already be thought of in the procurement.

The second report was published in 2004. The annual report Status of Healthcare was dedicated to patient safety in relation with medication en medical appliances. The ever-increasing complexity of medical appliances increases the number of possible treatments and improves the effectiveness of treatments. But the quality of the treatment – which is closely related to patient safety - is directly dependent of the quality, maintenance and proper use of the medical appliances. In the report it is stated that the guarantee of the quality, maintenance and proper use are at this moment not sufficiently guaranteed in the Dutch hospitals. The Inspectorate did not find evidence that risk assessments are done in a systematic manner for the whole life cycle of a medical appliance in Dutch hospitals. They did found evidence that hospitals use the advices of visiting accident insurers. As required by law, the hospitals should report failures with equipment to the manufacturer. The low number of reported failures of medical devices indicates that hospitals are under reporting at the moment. Furthermore there is no requirement to report failures in the introduction, management or maintenance to the manufacturer. The Inspectorate concludes that reliable statements based on the existing registration databases are not possible, making it impossible to know which type of medical appliances are unsafe for patients (IGZ, 2004).

The third report was published in 2005. The Inspectorate did a follow-up investigation on the report of 2002. The goal was to inspect if the boards took action to solve the problems mentioned in 2002, and how the boards used the report of 2002 for their plans of action. A few detailed outcomes from this report are summed up here, as these are of importance for a successful procurement (IGZ, 2005):

1. 32% of the hospitals do not have a clear procedure for the introduction of new devices. A hospital must be possible to guaranty that its personnel is competent and authorized to operate a device. The Inspectorate also marks that this is not obliged by the norms of the accreditation organisation NIAZ (in 2004).
2. In 55% of the hospitals it is not clear who coordinates preventive maintenance.
3. Only 52% of the hospitals plan to have documented procedures for the processes in the whole life cycle of medical devices, including budgeting, procurement, acceptation tests and training.
4. 74% of the hospitals have an acceptance test for new medical devices. The tests are focused on the technical side of the device, not the user side.

5. Release procedures for new or maintained devices are not present in 30% of the hospitals.

6. The availability of a proper Dutch user instruction is not planned to be available in 54% of the hospitals. This increases the chance of improper use of the device.

7. Educational procedures for personnel of instrumental services are clear at almost all hospitals.

8. 75% of the hospitals comply with Inspectorate rules concerning disparagement and replacement of medical devices.

All eight points here can and should be clear before procurement starts. Otherwise each procurement will have its own process to deal with these eight points. The quality of the procurement then completely depends on the capacity of the members in the procurement team. This would mean the procurement is not described nor guaranteed, which is illegal as stated in the Quality Law.

The fourth report was published in 2008. The Annual Status of healthcare was again dedicated to medical devices in cure and care. The report had two main problems:

1. Healthcare institutions are not aware of the risks of the use of medical technologies

2. Competence for the use of medical technologies is not present at the medical staff.

Both problems increase the chance of preventable adverse events. According to the Inspectorate, this will only increase in the future as healthcare becomes dependent on technology and technology becomes integrated and connected. As a result patient safety will only decrease in the future if nothing is changed (IGZ, 2008).

Therefore the Inspectorate gives recommendations to all parties involved to evade such a future; Ministry, representative parties, producers, expert groups and to itself. Here only the recommendations related to the problem definition (§ 1.3) are given.

In order to solve the problem of a lack of risk awareness, the Inspectorate demands that procurements should be based on a clear technology vision of the Board, a risk analysis before the actual purchase, and a good evaluation of the necessity of the device. During the procurement an implementation plan should be developed that also included periodic evaluation of the purchase. The evaluation should increase the knowledge for future procurements as well as intensify the use of post marketing surveillance contacts with producers. The last advice is that Boards organise a good system for the acceptance and release of devices for introduction and maintenance in hospitals. That should include technical evaluation, a validation of correct operation and a check if the device can be properly used by the organisation.

The status of healthcare also describes the role of the purchase department. Purchase departments currently have very diverse roles in Dutch hospitals. Even within a hospital can it be that other departments have different opinions about the task of the purchase department. The Inspectorate found that currently purchase departments are more of a broker, than a knowledgeable speaker for both the producers as for the department with a purchase wish. The purchase department should change into a ‘gatekeeper’ for the hospital, by preventing the introduction of devices that do not fit into the device vision of the board or introduce an unacceptable risk to the hospital. Furthermore the purchase departments should direct the whole procurement, including a process to form a good list of specification, and involve the needed expertise in the process necessary to make it a success.
In order to solve the problem of incompetent personnel, the Inspectorate advises the Boards to systematically check the competence and certificates of staff. As a user cannot become an expert of all the devices he is operating, the Inspectorate recognises the need for some kinds of system that can be used and checked by the user to assure himself that the device is function as it should. The Boards should organise such a system in negotiations with the users. A specific demand of the Inspectorate upon producers is also of importance in procurements: The producers should deliver a Dutch manual for a device that is written for the intending user and their knowledge level and the circumstances of use. This is of importance because user manuals at the moment are more like jurisdictional documents than actual manuals because of current regulations.

§ E.2 The Law on Medical Appliances and The Decree Medical Appliances

The Law on Medical Appliances (Wet op de Medische Hulpmiddelen) states what is illegal in the Netherlands and what measures the Minister of health is allowed to take regarding medical appliances. Basically it is illegal not to comply with the Decree Medical Appliances (Besluit Medische Hulpmiddelen). The Decree describes with what regulation a producer should comply in order to legally market a medical appliance. In this paragraph first the relevant parts of the Law and then of the Decree are summarized. The Law and the Decree are relevant as it provides definitions on medical appliances and it provides more information on what a hospital can expect from new products and from producers of these products.

Law on Medical Appliances


“… any instrument, apparatus or device, any substance or other article, alone or in combination, including the required software for its proper functioning, and that it is intended by the producer to be used with humans for the following purposes:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,
- Investigation, replacement or modification of the anatomy or a physiological process,
- Control of conception,

For which principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but such appliances can support this.”

This is a very wide term. It includes appliances you would expect, such as diagnostic equipment, surgical devices, hospital beds, disposable and sterile goods and injection pumps. But it also contains the electronic patient file systems. The definition has no clear border in case a doctor looks at an MRI photo on his own computer and not the computer that comes with the MRI scanner. Strictly taken the doctor would not be allowed to make a diagnosis when it comes from his computer screen, as the screen and computer is probably not intended not to be used as a medical appliance.

Decree Medical Appliances

The Decree Medical Appliances (1995) in Dutch Besluit Medische Hulpmiddelen, stems from a European directive called the Medical Device Directive (MDD, 93/42/EEG). It is translated into the
Appendix E  Govermental actions and regulations for quality of medical devices in the healthcare sector

Dutch language and law system with the Decree Medical Appliances. The Decree describes the regulation that needs to be met for a medical appliance to legally be traded in the Netherlands.


The first part of this sub-paragraph will describe the current legislation. That is relevant as it describes the regulation the hospital and the deliverers of medical appliances have to comply with. The second part will describe the legislation that will be activated on 21 March 2010. This is relevant as it is a change in the near future and thus relevant for this research that tries to provide a durable solution.

**Goal**

The MDD creates equal European regulation in the European Economic Area (EEA) for medical appliances and at the same time guarantees the safety of patients and user by demanding quality standards. All EEA nations have implemented the MDD in their own law system. This creates one equal market for medical appliances in the EEA. Only appliances with a proven quality standard (article 7, 9) will be provided access to the EEA market. To illustrate; producers from all over the world with a valid certificate of quality from a certification institute (article 11) of any EEA nation are allowed to offer that appliance in any EEA country (article 7, 9).

**Exclusions of the Decree**

The term ‘medical appliance’ is defined in the Law. The Decree is not valid for ‘medical appliance meant for clinical trial’, ‘build to fit medical appliances’ and ‘medical appliances that are indivisible of the drug they are meant to administer and may only be used once’. Furthermore the Decree excludes in-vitro diagnostics and implants. The former is part of the Decree in-vitro diagnostics (*Besluit in-vitro diagnostica*) and the latter is part of the Decree Active Implants (*Besluit Actieve Implantaten*).

**Conditions to market a medical appliance**

In order to market a product on the European market, the appliance has have a CE mark on it. It can only have a CE mark on it, if it complies with the relevant demands as stated in the Decree (appendix part 1), and other relevant norms and safety requirements valid on a European level (article 6). The demands stated in the Decree are on essential safety requirements for user and patient, acceptable risks compared to the purpose and efficiency and effectiveness of the technical and clinical performance. For all medical appliances it is obligated to prevent and if not possible minimize impacts for patients and personnel of possible hazardous events related to the use and maintenance of the device, for example wear by frequent use, fluids entering (appendix part 1). Type one errors must be foreseen by the producers and may not cause damage to user or patient.

Specific demands are in place on construction, sterility if the appliance is marketed as sterile, biocompatibility if the appliance comes in contact with the human body, radiation if the appliance radiates and energy safety if the appliance uses energy.


A Dutch addition to the MDD stated in the Decree is that providers are obligated to provide a Dutch manual that is understandable for the intended user. For a device of classes I and II/a it is not obligated for the producer to provide a manual, if the use can be explained with writings and icons on the appliance itself. The manual should contain a description of possible sources of interference with other medical appliances that can be expected to be near another in medical procedures, and interference with energy sources outside the hospital in the case of implantable devices. Furthermore it should contain warnings on what can be done against interference and what should be done when the device malfunctions. Another Dutch addition to the MDD is that radiating devices should be conform with the Nuclear Energy Law (Kernenergiewet).

Hospitals are only allowed to buy medical appliances that are certified (article 4), unless it is an appliance for clinical research or a by the producer build to fit appliance (article 3, 7). Producers are legally responsible for the performance of the machine, but only if the user operates the machine as described in the manual.

**Classification and conformity procedure**

The producer has to follow a so-called conformity procedure to prove that it complies with the demands of the Decree and relevant norms (article 9). The strictness of that procedure depends on the risks that come with the device. The appliances are divided in four safety classes (Article 8). From low risk to high risk that are class I, II/a, II/b and III. The rules of classification are stated in the Regulation for Classification of Medical Appliances (Regeling classificatie medische hulpmiddelen). In general, class I is for appliances that are non-invasive devices, and cleaning devices. Class II/a and class II/b are for appliances that are invasive. Depending on their impact are they classed as a or b. Class III is for invasive appliances with a direct effect on the blood system and nerve system, as well as long-term implantable appliances. For more details on classification, see Appendix C. The producers themselves determine if their product is a medical appliance, for what the appliance can and cannot be used (article 1) and to which class the appliance belongs (article 8). Their decision on class can be overruled by the authorities or by the notified body.

The Decree prescribes the conformity procedure based on a class an appliance belongs to (article 9):

- For class I, the producer should make a product file in which it is proven that the device complies with the relevant demands. This file must be available for the Inspectorate. The producer himself states that the product complies and then brings a CE mark on the product.

For class II/a, II/b and III a producer contacts a notified body (in the Netherlands that are KEMA and TNO) who approves the product and allows the producer to put the CE mark on the product. On what basis a notified body approves an appliance, depends on the class a product is in, as well as the preferred procedure for the conformity procedure. There are several procedures to prove that a product is conform with the relevant norms (article 9):

- Class II/a appliances have two possible procedures to prove conformity:
  - Appraisal of notified body of the quality system of the producer, which includes proven mastering of the design procedures and a proven mastering of the production process
  - A intensified producer statement of conformity, together with an appraisal by the notified body of the:
    - proven mastering of the production process
- in series build medical appliance based on an inspection
- proven mastering by the producer of inspection of the in series build medical appliance
  
o Class II/b appliances have two possible procedures to prove conformity:
  • Appraisal of notified body of the quality system of the producer, which includes proven mastering of the design procedures and a proven mastering of the production process
  • An appraisal of the notified body of a tested appliance, together with an appraisal of:
    - proven mastering of the production process
    - in series build medical appliance based on an inspection
    - proven mastering by the producer of inspection of the in series build medical appliance

  o Class III appliances have two possible procedures to prove conformity:
    • Appraisal of notified body of the quality system of the producer, which includes proven mastering of the design procedures, a proven mastering of the production process and an appraisal of the design itself
    • An appraisal of the notified body of a tested appliance, together with an appraisal of:
      - proven mastering of the production process
      - in series build medical appliance based on an inspection

Post marketing surveillance
For all medical appliances it is obligated to have a post-marketing surveillance system. This system includes a contact desk for users to report (near) incidents with the appliance, a file in which all (near) incidents related to the appliance are documented, and possible improvements to the device based on the documents. Furthermore the producer should actively ask users how the device is functioning.

Update of the law in 2008
The Decree is updated in 2008. This update is active from 21 March 2010. The updates that are related to procurements in hospitals are:

1. User orientated design: Already in the design of the medical appliance has the producer the obligation to focus on safety aspects, by anticipating and mitigating user errors. Furthermore is the producer obligated to keep the technical knowledge, experience, education, training and medical and physical fitness in mind when designing an appliance. For class II/a/b medical appliances, the design dossier also has to be presented to the notified body for certification.

2. Scientific evidence: for all medical appliances it is obligated to do a clinical evaluation to comply. This evaluation has to be updated during the time the product is marketed. Class III appliances and implants need to be evaluated on basis of clinical research.

3. Next to software supporting appliances, also stand alone medical software has to be CE certified and tested with the most advanced test methods.

4. All appendices are not in the Decree itself anymore, but in the MDD, 93/42/EEG. The Regulation of Classification document is not valid after 21 March 2010. The classification principles can be found in the MDD as well. The goal of this is to improve implementation speeds of changes in the whole EEA area. For hospitals this means that the true meaning of CE can be found in the MDD.
APPENDIX F. PROCUREMENT EXAMPLES

This appendix presents procurements that were discussed during interviews. Some were discussed in more detail than other.

For each procured device presented here, its risk class stemming from the Regeling Classificatie Medische Hulpmiddelen (Regulation for Classification of Medical Devices) is given, to provide the reader with a notion on how the regulation judges the risk of a particular device. If it is known, the budget class is also given.

§ F.1 Syringe pump

The syringe pump is a class II/b device, as it is meant to change chemical and biological composition of the blood with use of medicine. The total budget was above one million, so it is a C investment.

The initial procurement was for 500 units. More have been ordered after the first order was complete, which was not part of the initial budget. The syringe pump is used on many different departments and many different users operate the device (nurses, doctors, anaesthetist) with different backgrounds.

The syringe pump was already discussed in § 1.3.2. The syringe pump initially was a request of one department, and the procurement process was scaled up to serve several departments in 3 divisions. It was a replacement of an old pump.

Requirements

Besides the regular function of a syringe pump, this new pump should be able to communicate over the network for medicine prescriptions per patient. During the procurement several things went wrong (Koornneef, 2008)(LUMC internal report):

• The assortment coordinator was not part of the project group, while it is seen as part of his job to accompany procurements
• During the specification of requirements several sub-committees were formed to specify requirements about specific topics, such as users and medicine. The procurement team did not have a discussion with the sub-committees, which disappointed some sub-committee members, but also hindered the clear and proper transfer of the requirements
• There were no clear goals for deliverables and reports developed for the sub-committees, nor was it clear to them that they were formulating requirements for a European tender
• The distinction between the succeeding project groups for the different phases in the procurement, mutually, and in relation to the steering group, were not clearly defined
• The program of requirements for the tender was ambiguously defined. As a result it could be interpreted differently
• The user tests were not designed to test and discover errors with critical functions
• The evaluation of the device in the test period was not done properly, although this was part of the program of requirements
This is a long list of thinks that could have been done better in this procurement. It is presented here to make the reader clear that a lot can go wrong in one procurement. The interviewees were asked to give their opinion about the procurement.

Cause of problems

Seen from the view of the clinical technology department, the syringe pump procurement had a great deal of flaws in recognising and dealing with the increased complexity of a syringe pump. It had evolved from a simple pump (old pump), into a complex pump with network communication possibilities (new pump). The risk assessment only dealt with the device, not with the other devices it connects with. Flaws were also made by the difference in perception of terms between the different departments, when talking about ‘the syringe pump’ and its requirements. In the end all three divisions involved were not satisfied with the procured pump, although all three agreed on buying it. Another difference is that no one was really dedicated to the syringe pump. It was for everyone, so nobody was dedicated. In earlier procurement for syringe pumps, someone of the pharmacy store was involved. The pharmacy staff member was an expert with these things. This secured pharmaceutical knowledge in the procurement process. A last source of flaws was the lack of communication between subgroups and the procurement team.

The chamber of non-sterile medical devices of the CMC requested involvement several times in this project, but was turned down every time, with the argument that the project was almost at an end and did not require any more attention. The chamber was of opinion that it is possible to prevent the problems of the syringe pump by performing well based user tests.

Financial discussion

There exists disagreement about the class the procurement was classified. The syringe pump project was an exploitation project of old syringe pumps. An individual pump was not even a B investment, so there is no need for it to be discussed with the board. The only reason the syringe pump project came into the board, was that the complete budget for the procurement was above the line of a European tender, €250k. But at the same time the total budget was a type C investment. It was worth more than 1 million euro.

There is a financial explanation for the difference. The two reasons the budget for the syringe pump was presented to the executive board was because it was a European tender done by three divisions, and that it was a project that could not be paid out of the lump sums of the divisions themselves. So an extra request of budget was asked from the board. It was chosen to replace all pumps at once, as this would improve the quality. So, the pump should have been paid by each involved department, leading to several smaller investments, while the total project was worth €1 million.

Aftermath

It was discovered that the brief version of the manual for the user does not describe the same safety procedures as the main manual. The original manual is CE certified and large, which makes it impractical in use. Therefore brief version manuals are written for the user. For the syringe pump it missed essential safety warnings and prescriptions. A group in the hospital now is active in teaching how the users how to operate the pump. In this situation the original manual serves as a legal document for the producer., and so does the brief version.
§ F.2 Beds for the whole LUMC

Beds are medical devices meant to support the patient, but have no further interaction with it. This makes it a class I medical device, but there still is a risk for patients to fall out of bed. The beds were procured for the whole LUMC, and is thus an C type investments

The procurement of the new bed was initially carried out together with the VU University Medical Centre. The whole requirements specification was performed together, although some specs differ. One important difference between the two hospitals was how the beds are going to be cleaned. The VU University Medical Centre cleans their beds at one central location. The LUMC has chosen to change from a central cleaning location to local cleaning on the medical departments. This difference has not led to a different supplier between the medical centres. The decision to clean the beds locally is based upon a risk assessment and discussion with the central protocol committee.

At this moment the beds are being introduced into the hospital. Five defects are detected during the procurement and during the introduction and use. First, the computer controlled adjustment would only let the bed to be moved up, not down. This was discovered before the introduction. The other three defects were discovered during use. Second, the adjustable popinjay (handle above the bed) could suddenly break and drop down if the patient uses it, and as a result falls down on the patient. Third, the handle to lower the bed in emergency situations was directly accessible in such a way that it is possible to lower the bed onto the arms of the user of the handle, and by that at least contusing its arms. Fourth, the rail that protects the patient from falling out of bed is placed in such a way that it is almost impossible not to hurt ones hands when lowering the rail. Fifth and last, the beds have many cavities, making it hard and time consuming to clean them. Some parts are even impossible to reach.

The cause that these defects are not discovered with the acceptation test lays in the fact that acceptance test regarding these issues were not specified in the first place..

§ F.3 Suture for the operating theatres

Suture is a disposable product. It is not known if it is paid out of the LUMC budget or the insurance system. As suture is a product that is constantly being procured, it is hard to classify it in a product category. It is seen as a class II/a or a class III medical appliance, depending were it is used on the human body

The procurement of suture is also a procurement carried out with another hospital, the Rijnland hospital. At the moment user tests are performed on all the surgeries from certain disciplines. A company that has the smallest market share in the Netherlands won the tender for suture. Although the tender is already finished, it is still possible that because of issues in the user test the procurement will not continue. It will be difficult to stop the purchase, as it is not only the suture that has to comply with the surgeon, but also the surgeon that has to adapt to the suture. It is hard to prove that it is only the suture that is causing trouble. The user test then also becomes a learning phase for the surgeons. If the surgeons are adapted to the suture, there is still the chance that they simply do not like it. This is a criterion with a weak jurisdictional power, as it is a subjective opinion.

The suture is going to be procured for the operating theatre department. Surgeons, specialists and OK nurses use the suture. Apart from a few exceptions, all the different surgeon disciplines will make use of it. It is a disposable product that needs to be sterile until it is used. It will be reordered whenever the stocks are low, without there being a new procurement team to again market their demand for
suture, as this is too resource consuming. It was decided this time to make it a tender, as the other producer of suture has a very high market price.

A clear indicator for the wish for a new suture comes from the fact that another (new) producer entered the market offering a significant lower price for medical suture. It is a product that is provided by supplier continuously (for example, monthly), and as a product type it does not has a clear end of life. This time a cheaper alternative was the indicator.

§ F.4 Cochlear implants for the Ear-Nose-Throat (ENT) department

Cochlear implants are active medical devices, which are partly placed inside the human body for a long time, making this a class III device. They are bought per unit, with low numbers a year. It is not an investment, as it is directly paid by the insurance system.

There are several producers of cochlear implants. The supplier is chosen according to the need of each patient. The ENT department specialist, in consultation with the audio experts who have thorough knowledge about cochlear implants, makes the choice. The specialist never involves other departments for the procurement of cochlear implants, as his own department knows every aspect of a cochlear implant, the technical details, the user requirements and the audio requirements.

§ F.5 Electronic Patient file System (EPD)

The EPD software is a local implementation of a national wide network of EPD systems. The EPD is a class I medical device. The price depends on what is included in the purchase, for example building and installation costs, training of personnel and purchase of additional terminals to access the EPD. It is estimated that all costs together are at least a type C investment.

It is one software package, which is used by all the personnel of all departments, with different authority levels and knowledge levels. Privacy is a crucial point for the success of the EPD. Furthermore it needs to function on several different distributions of several operating systems that are in use in the LUMC. It is a system with far reaching consequences for the working processes in the LUMC. It thus influences other systems, and is influenced by other systems.

The project was ongoing during publishing. It is carried out together with other Dutch hospitals. The LUMC staff consults with external experts about the procurement.

§ F.6 Coagulate time indicator

The coagulate time indicator is a class II/a device, used during surgery to have an indication of the coagulate time values. It is a procurement that is an A type investment and the budget is received as part of the lump sum of the radiology department, and approved by the head of radiology. The purchase department checked if it was a standard item with a preferred supplier (it was) and ordered it. It operates as required. The coagulate time indicator is a simple product, as it provides one type of data, the coagulate time.

§ F.7 Angiography room

The LUMC has two angiography rooms. One room has been rebuilt with new devices and a new layout. It was done by first placing the new device and then remove the old one, so to be able to provide care to patients continuously.
A room in itself is not a medical device. Here the LUMC clearly procures a function, with in it some medical devices, but also a certain lay out and protection. It is not know which devices specifically are procured for this room. The budget for the whole room is of investment type C, but it could be that the devices alone are of lower investment classes. The medical devices that enter the body (for the surgery) are of class III. The X-ray scanners are of class II/b.

§ F.8 PACS system

PACS (Picture Archive and Communication System) is a class I medical device. Its investment type is not known, but it is estimated that it is at least a B type investment.

The PACS system is primarily meant to store and spread the images that are made by radiology. The primary users are therefore spread throughout the hospital, with several levels of authorization and different levels of experience of users. The PACS software is maintained by the facilitating services of radiology, while the servers it is running on is maintained by ICT. The PACS system is a software package, which are seen as class I devices.

The PACS system was procured by the facilitating service department of radiology, in cooperation with the ICT department. It still provides some trouble, as the user interface is not designed with the actual user in mind. There are no troubles known with the system itself.

§ F.9 New Intensive Care (IC)

The LUMC planned to build new ICs. A test IC was build, to test if the design was right. A few essential things had to be changed in the design. Furthermore, TNO was asked to study the airflow in the IC. Some interviewees see it as a good example how tests should be done; by making test cases.

A room in itself is not a medical device. Here the LUMC clearly procures a function, with in it some medical devices, but also a certain lay out and protection. It is not know which devices specifically are procured for this room. The budget for the whole room is of investment type C, but it could be that the devices alone are of lower investment classes.

§ F.10 Neonatology telemetrics

Telemetrics is used to monitor a patient real time at a distance. The measurements are done at the patient, and are monitored at a central location. The connection between the sensor and the monitor are present in two variants, wireless and wired. The telemetrics for neonatology is wireless. As it monitors vital life signs, it is a class II/b product. It is bought for the neonatology department only, in small numbers. It is not known if it was a type A or B investment, most probably a type A investment, for reasons named here below.

The telemetric equipment was procured and installed without ICT being involved. After being in use for already some time, the system experienced signal disruptions. As the clinical technology department could not solve the problem, they contacted the ICT department. ICT discovered that the problem was a not well functioning microwave. During their investigation, ICT also discovered that the assumptions for the telemetric network were not in line with the LUMC network. Other wireless devices could lead to more signal disruptions on the telemetric network. ICT could not accept the use of the telemetric devices. It required a redesign of the producer to make it possible to make it function in compliance with the LUMC network.
It is assumed that it is an A type investment, as the ICT department was not aware of the procurement. For a B type investment ICT would have been aware by the use of the budget form.

§ F.11 Telemetric ECG

This telemetric system for cardiology monitors vital life signs of patients. Therefore it is a class II/b product. It is procured for the cardiology department alone. It is not known what investment type it was, but as with the telemetrics for neonatology, the ICT department was involved too late. Therefore it is assumed it was a type A investment.

The ICT department was involved when it was required to provide some network supplies. Then ICT discovered that the network topology for the telemetric device was not compatible on all aspect with that of the LUMC. This would create a non-workable system for cardiology. ICT has therefore put a no-go on the project, unless changes were made to the telemetric system.

In this project the ICT department was involved when his department was asked to supply some services. After a while it turned out that the network of the producers was not compatible enough to provide the cardiology department with a working telemetric system. ICT has put a no-go on the project, unless the product was changed.

As a principle, wireless telemetrics will never provide the guaranteed quality as wired telemetrics would give. It is therefore questionable in to use real-time telemetrics in combination with a wireless network, as there is not a guaranteed throughput real-time possible.

All network norms are present in norms and protocols. So during the procurement, the procurement leader could have specified this in the requirements list. It is not found why this is not done.

For the end user the introduction of the telemetric system just takes too much time. The problem is not clear to the end user, except that it has to do with the network. In the eyes of the end user, the procurement was an easy process, as only one telemetric system producer could deliver a system that was compatible with the network of the LUMC.

The end user was only involved in the procurement, by specifying user requirements, like type of battery and number of devices.

This is an example of a procurement that was changed during the procurement. It shows the dynamics of procurements. Even though a budget decision is taken, still it is possible to change ones request. It is not known what is done with the budget form and the granted budget, if the device wish suddenly changes.

§ F.12 Anaesthetic monitoring device

An anaesthetic monitoring device is a class II/b device, as it monitors vital life signs. It is operated by anaesthetist and only on the operating theatres. When a patient is operated, a life monitor registers the life signs, while a breathing apparatus takes over the lung functions and measures parameters of the lungs. A procurement project was started to buy an integrated device. It soon turned out that the costs would require a European tender. During the tender it was found out that a separated (instead of integrated) device would better serve the needs, while the costs were lower. It was discovered during the procurement that this was the best option.
Figure G.4: Explicit causal diagram
### Table G.1: Factor List

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<th>Optional Information</th>
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<td>Costs per adverse event</td>
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<td></td>
<td>Preventable deaths</td>
<td>deaths / year</td>
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<tr>
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<td>Incident costs</td>
<td>€ / year</td>
<td></td>
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<td></td>
<td>Maintenance costs</td>
<td>€ / year</td>
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<td>Purchase costs</td>
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<td></td>
<td>Failures of interaction user-device</td>
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<td></td>
<td>Failures of organisation</td>
<td># / year</td>
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<td>year</td>
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<tr>
<td></td>
<td>Maintenance frequency</td>
<td># / year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maturity of device technologies</td>
<td>years</td>
<td>Specific for the producer, the youngest technology</td>
</tr>
<tr>
<td></td>
<td>Mean time between failures</td>
<td>hour</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Price per device</td>
<td>€ / device</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quality of the device materials</td>
<td>[scale]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Required infrastructure</td>
<td>€</td>
<td>If it are annual costs = [€ / year]</td>
</tr>
<tr>
<td></td>
<td>Required utilities</td>
<td>€</td>
<td>If it are annual costs = [€ / year]</td>
</tr>
<tr>
<td></td>
<td>Time per maintenance routine</td>
<td>hour / device</td>
<td></td>
</tr>
<tr>
<td><strong>Usage characteristics</strong></td>
<td>% of fulfilled requirements</td>
<td>%</td>
<td>(available) / (requested) * 100</td>
</tr>
<tr>
<td></td>
<td># of departments</td>
<td>#</td>
<td></td>
</tr>
<tr>
<td></td>
<td># of treatments</td>
<td>#</td>
<td></td>
</tr>
<tr>
<td></td>
<td># of treatments per department</td>
<td>#</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Actions per treatment</td>
<td># / treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Availability of personnel</td>
<td>hour / year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Available treatment time</td>
<td>hour / year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Experience of user</td>
<td>[scale]</td>
<td>Per specific device</td>
</tr>
<tr>
<td></td>
<td>Peak utilization</td>
<td>#</td>
<td>maximum # of devices in use at the same time</td>
</tr>
<tr>
<td></td>
<td>Required amount of devices</td>
<td>#</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Satisfaction with device</td>
<td>[scale]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time per treatment</td>
<td>hour / treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment Costs per time Unit</td>
<td>€ / hour</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total treatment time</td>
<td>hour / year</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>% of changed protocols</td>
<td>%</td>
<td>(changed protocols) / (required to be change) * 100</td>
</tr>
<tr>
<td></td>
<td>% of personnel trained</td>
<td>%</td>
<td>(trained personnel) / (required to be trained) * 100</td>
</tr>
<tr>
<td></td>
<td>Training level of user</td>
<td>[scale]</td>
<td></td>
</tr>
</tbody>
</table>