The perception of stakeholders on the compliance and functionality towards patient safety enhancement on Productdossier in hospitals in The Netherlands

A qualitative study in two Dutch hospitals towards the perception of employees in a hospital on compliance and the functionality of the Productdossier

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Preface

Healthcare fascinated me since I was young, and therefore Health Sciences at the University of Twente was a logical choice. I learned that healthcare and especially delivering quality in healthcare is not as straightforward as it seems. This report describes my master thesis "The perception of stakeholders on the compliance and functionality towards patient safety enhancement on Productdossier in hospitals in The Netherlands".

The assignment at Isala in Zwolle offered to me was a great experience to extend my knowledge regarding patient safety enhancement. I would like to thank the purchasing department of Zwolle for their assignment, and especially I would like to thank Ronald Buisman for his guidance. Also, I would like to thank Máxima Medisch Centrum for their participation in this research. I am very thankful for the enthusiasm and contribution of all respondents. Next to that, Also, I am grateful for the employees of the other six hospitals in The Netherlands that participated in the preliminary research and guided me through their process concerning the Aanschafdossier and Productdossier. I hope the hospitals in The Netherlands continue sharing their knowledge. Also, I hope this research on the compliance burden and functionality of the Productdossier contributes to the quality of care in hospitals and reduces the number of incidents regarding medical equipment or medical technology.

I would like to thank both my supervisors at the University of Twente, Gréanne Leeftink and Frederik Vos. Both supervisors were enthusiastic and helped me through the entire process. I appreciate Gréanne's positive approach and all feedback she provided. Frederik contributed as a supervisor with his knowledge and input from different perspectives.

Also, I would like to thank my fellow colleague-students of Isala: Josien Mourik, Max Kloosterman, and Leon van Beek. Thank you for reviewing and reading my research, and for helping with the pilot interviews. I would like to thank my colleagues from the purchasing department for their support and engagement in my research. I enjoyed walking together during the lunchbreak in the beautiful area around Isala. Also, I am grateful to my friends and family for their support, contributions and their curiosity.

Last, I would also like to thank you, my reader: I hope you enjoy reading!

Judith de Boer

Zwolle, 14th of March, 2023

Summary

This research evaluates the perception of stakeholders on the Productdossier as part of the Aanschafdossier by use of theory on *red tape,* regarding the terms *lack of functionality* and *compliance burden*. We use a descriptive cross-sectional study design, by collecting qualitative and quantitative data through the use of semi-structured interviews. We interviewed eleven respondents from two from "Isala" and "Máxima Medisch Centrum" and analysed the data by a hybrid coding strategy of inductive and deductive thematic analysis.

This research concludes stakeholders perceive the components of the Productdossier as functional in enhancing patient safety in hospital while experiencing a high compliance burden. The Productdossier in general is positioned in the quadrant necessary bureaucracy of the red tape scale. Component 1, 2, and 3 of the Productdossier can respectively be found in the quadrants unnecessary rules, red tape, and necessary bureaucracy. Component 4 and 5 can be found in between unnecessary rules and red tape due to the variance of perceived compliance burden of the respondents.

Hospitals should reduce the compliance burden to alter a shift from *necessary bureaucracy* towards *high-quality rules* on the red tape quadrant. We recommend redesigning the process, make a distinctions in the risks and costs of products, establishing barriers to control the quality of the Productdossiers, reduce the number of applicants and better educate them. Also, we advise to designing a periodic evaluation plan, and lastly we recommend to look for collaborations with other hospitals in The Netherlands.

Keywords: Aanschafdossier, Productdossier, Convenant Medische Technologie, Red Tape, patient safety, healthcare

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1. List of abbreviations

Abbreviation	Definition	Original Dutch definition
AOC	General object classification	Algemene Object Classificatie
ASHE	American Society for Hospital Engineering	
BIG	Individual Healthcare Professions	Beroepen in de Individuele Gezondheidszorg
CBMH	Committee for assessment of medical devices	Commissie Beoordeling Medische Hulpmiddelen
Covenant	Covenant Safe Usage of Medical Technology in the Medical Specialistic care	Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg
DAB'er	Decentral inventory controller	Decentraal assortimentsbeheerder
DSMH	Experts Sterile Medical Devices	Deskundigen Steriele Medische Hulpmiddelen
IC	Intensive care	
ICT	Information and communication technology	
IGJ	Health and Youth Care Inspectorate	
IoM	Institute of Medicin	
IZZ	Instituut Ziektekostenvoorziening Ziekenhuiswezen	
JCI	Joint Committee International	
MAC	Material Advisory Committee	Materiaal Advies Commissie
Máxima MC	Maxima Medical center	Máxima Medisch Centrum
MHC	Medical Devices Committee	Medische Hulpmiddelen Commissie
NFU	Dutch federation of University Medical Centers	Nederlandse Federatie van Universitair Medische Centra
NVZ	Dutch association of hospitals	Nederlandse Vereniging van Ziekenhuizen
OK	Operating room	Operatiekamer
PDCA	Plan Do Check Act	
PREMs	Patient-reported experience measures	
PROMs	Patient-Reported outcome measures	
VIM	Safe Incident Reporting	Veilig Incident Melden
VMS	Safety management system	Veiligheidsmanagementsysteem

1. Introduction

In 1999, the study report *To Err is Human: Building a Safer Health System* published by the Institute of Medicine (IoM) highlighted the safety of patients in hospitals [2]. 98.000 patients died due to medical errors each year, which was the 8th-leading cause of death in the United States. The revelation of the high number of medical errors caused the Dutch organization for Medical Specialists to examine health system safety in the Netherlands. In 2007, around 30.000 patients in The Netherlands were affected by medical errors resulting in harm, of which 1735 patients died [3]. Since then, the national *Veiligheidsmanagementsysteem* (VMS) ('Safety management system') was introduced to reduce the incidence of medical errors and quality of care received more attention. In 2017, in total 73 incidents were reported related to equipment, material, and ICT in The Netherlands. In 2021 this is reduced to 49 [4].

There is an increase in the usage and importance of medical technology and medical devices in healthcare noticeable. Medical technology and medical devices entail risks of harming and injuring the patient and the employees, and therefore also affect patient safety. This happened for example in the Netherlands in the past with a fire at the operating room of the hospital in Almelo, a negligent purchasing process and implementation of surgery robots, and the usage of mesh to treat women suffering a pelvic organ prolapse [5]. All three incidents share the cause of a lack of quality and safety systems for medical technology. These three are high-profile cases, yet mistakes occur regularly in healthcare organisations [6]. To accompany the safe use of medical technology and medical devices while maintaining high quality for patients, the *Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg* was established [7] ('Covenant Safe Usage of Medical Technology in the Medical Specialistic care' in English, in the remainder referred to as 'the covenant'). The Covenant encompassed agreements regarding the safe use of medical technology in medical specialistic care. The Covenant is published in 2011 by the *Nederlandse Vereniging van Ziekenhuizen* (NVZ) ('Dutch association of hospitals') and the *Nederlandse Federatie van Universitair Medische Centra* (NFU) ('Dutch Federation of University Medical Centres') and controlled by the *Inspectie Gezondheidszorg en Jeugd* (IGJ) ('Health and Youth Care Inspectorate') [7]. Its intended goal is to safely use medical technology in medical specialistic care by use of safe products that are used by trained users in a safe environment.

To meet the agreements in the Covenant, every hospital in the Netherlands is obliged to create a process that documents the selection of medical devices or a group of medical devices. A lot of hospitals

call this the *Aanschafdossier* (‘Procurement File’). We decided to retain a few Dutch terms for the remainder of this report, for clearance and total covering of the content. The Aanschafdossier consists of a fitting workflow concerning the introduction, usage, preventive- and corrective maintenance, evaluation, and rejection. It helps to fit the requirements of the Covenant. The Aanschafdossier is described as a framework of processes to perform a set of actions before ordering and using a new product in a hospital. One of these actions is to create the *Productdossier* (‘Product file’) on which we will focus in this research [7]. This entails five components according to the Covenant: the need for the new product (1), product requirements document of the healthcare facility (2), risk analysis (3), competency requirements and corresponding education of future users and technologists (4) and a periodic evaluation plan (5). We will further elaborate on each of the five components in Section 2.3.

Preliminary research in eight Dutch hospitals showed the workflow for the Aanschafdossiers varies between hospitals, as can found in Appendix K. There is no golden standard for Aanschafdossiers, as each hospital requires a customised process due to the complexity and specificity of hospital systems and because of the high number of disciplines involved in the process. Hospitals continuously improve and monitor compliance with the Covenant. This is perceived as a problem, as it takes much time and effort. So are the hospitals that are participating in this research: *Isala* and *Máxima Medisch Centrum* (Máxima MC). Isala evaluated their Aanschafdossier in 2022 [8]. This evaluation highlights that the purchasing process is currently not efficient and does not completely fit the agreements of the Covenant. The entire process from application to usage of a new product requires much time, effort, and dedication from a high number of employees of various disciplines. Máxima MC is currently improving its process because of the same reason. Also, it does not fit the Covenant and the involvement of the right disciplines at the right moment is not working.

Research shows that healthcare workers experience a regulatory burden in healthcare as a result of administrative procedures alongside the delivery of care [9]. The increasing administrative burden negatively influences the functioning and job satisfaction of healthcare professionals [9]. A theory that corresponds to administrative burden by evaluating the *lack of functionality* and the *compliance burden* of a set of rules is *red tape* [1, 9-12]. This theory will be further elaborated on in Section 2.4. This research uses red tape to evaluate the perceived functionality of the Productdossier in relation to the experienced burden. The research question addressed in this research is:

“In how far do stakeholders in hospitals perceive the Productdossier as functional and as burdensome, and how could this be improved?”

This research is unique due to its methodology as described in Chapter 3 and adds scientific and practical contribution. This research concludes the Productdossier is functional for patient safety enhancement, while having a high compliance burden. Other researchers evaluate the quality of other actions aimed at prevent safety incidents, but none evaluates the Aanschafdossier nor the Productdossier as a separate action that prevents safety incidents. This research extends on Schoten et al. [13] towards healthcare-related damage within deceased patients in Dutch hospitals. Also, this research supports the usage of the Covenant. This research also has practical relevance. We noticed that due to the high compliance burden noticed in this research, we provoked a discussion. Currently, Isala started changing their process. In Section 5.25.3, we further elaborate on the scientific and practical relevance of this study.

The structure of this report is as follows. Chapter 2 provides the literature review on the background of this research about quality management, innovations on quality enhancement in hospitals, the Productdossier, and red tape. Also, in this chapter, we describe our expectations for the outcomes of this research using literature. Chapter 3 discusses the methodologies for this research, by discussing the interview guide, sampling, and the analysis strategy. Chapter 4 describes the results of this research. In Chapter 5, we answer the research question and discuss the results of this research. Also, we provide recommendations for hospitals and further research in this chapter.

2. Theoretical framework

This chapter reviews the theoretical framework on quality in healthcare regarding the Productdossier. In Section 2.1, we discuss quality management. First, we describe quality management in general. Next, we focus on quality management in the healthcare sector, the effects of quality management, how safety incidents occur despite quality management according to the Swiss Cheese model and how quality is evaluated. In Section 2.2, we discuss actions that prevent the occurrence of safety incidents. One of these actions discussed is the Aanschafdossier. Section 2.3 elaborates on this specific action by addressing the Productdossier and its five components. Section 2.4 elaborates on red tape, the consequences, and the causality to healthcare. Red tape is used in this research to evaluate the perception of employees on functionality and compliance of the Productdossier. Section 2.5 concludes the literature study.

2.1 Quality management

Several advantages of quality management are customer satisfaction; product quality and reliability; efficiency; productivity; growth in earnings; and customer satisfaction [14]. Several programs are established to focus on quality management: Quality Control, Total Quality Management, Continuous Quality Improvement, reengineering, and Six Sigma. These programs all include data gathering, analysis, and statistical monitoring to identify the problem and its cause.

The regulation of quality differs among sectors. This report focuses solely on the healthcare sector. Quality management in healthcare is complex, as it contains multiple interacting systems that are connected within complex networks of individuals, teams, procedures, communications, equipment, and devices [2]. All these systems function with diffused management in a variable and uncertain environment. Variability is inherent in patient care due to patient characteristics and fluctuating demand for care [6]. Also, in healthcare, there is a high need to adapt processes rapidly. Additionally, knowledge is changing quickly [2].

Quality regulation in healthcare is important to achieve better patient outcomes, patient satisfaction, and it can lead to significant financial advantages [15]. According to the IoM, quality of care is “the extent to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” [6]. Quality of care is outlined by the IoM into a framework consisting of seven domains: safety, effectiveness, patient-centeredness, timely,

efficiency, equitably, and integration [15]. In this report, we focus on the safety domain. Patient safety is defined as "the (near) absence of (the risk of) patient injury due to the substandard performance of health care professionals and/or shortcomings in the health care system" [16]. This domain has the incentive to avoid harm to the patients for whom the care is intended [15]. To ensure the quality of care, hospitals should prevent adverse events, errors, and accidents. An adverse event is "an injury caused by medical management rather than the underlying condition of the patient" [2]. An error is "the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)" [2]. An accident is "an event that involves damage to a defined system that disrupts the ongoing or future output of that system" [2]. In the remainder of this report, the term "safety incidents" is used to combine these three terms. Safety incidents are prevented using good organizational design and different layers of defences, barriers, and safeguards. However, in some circumstances, safety incidents are unpreventable. Despite the presence of sophisticated systems, healthcare workers must be aware of human error and negligence. To improve quality, it is important to acknowledge that actions aimed at safety incident prevention never guarantee 100% prevention. Also, there needs to be respect for human limits regarding accident avoidance [2].

Separate actions aimed at safety incident prevention are difficult to evaluate, as safety incidents occur according to the *Swiss cheese model* [17]. This human error model by James Reason explains the occurrence of safety incidents that happen due to multiple defects in actions that aim at safety incident prevention [17]. A layer of defence is compared to a slice of Swiss cheese, having holes (or defects) in the cheese (or in quality management). Figure 1 illustrates this model. One single hole does not immediately cause safety incidents, often this happens when there are multiple consecutive holes. Measuring these holes is a metaphor for the measurement of outcomes across the causal chain in organizations. The defects arise for two reasons: active failures and latent failures. IoM states technology also has to be recognised as a member of the work team, as it also performs tasks and changes the interaction between other team members [2]. Therefore, the Swiss cheese model applies to the medical technology for which the Covenant was initially developed. Figure 1 shows the multiple layers of defence to prevent safety incidents, whereby the green bullets present the hazards. The figure is adapted to this research, using components of the Productdossier at the top of the image and general actions that contribute to incident prevention at the bottom of the image. Section 2.2 further elaborates on multiple examples of layers of defence in the prevention of safety incidents. In Section 2.3, we specifically discuss the components of the Productdossier.

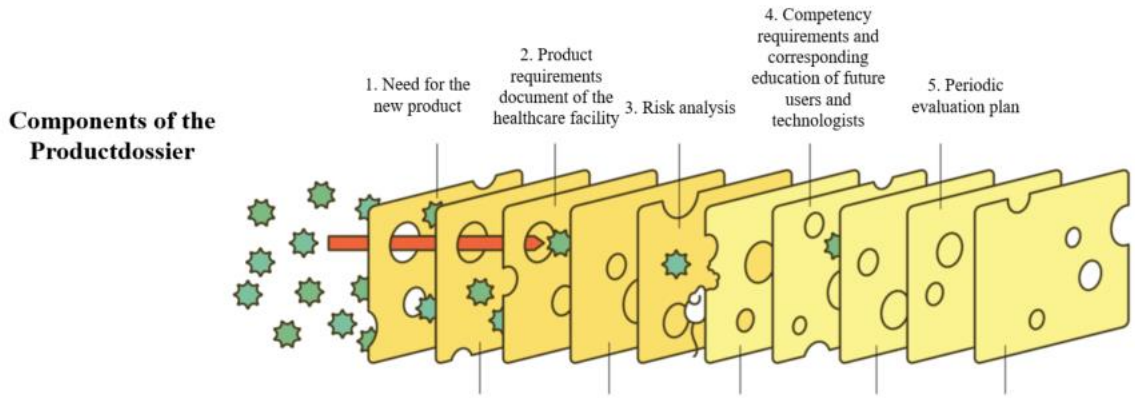


Figure 1 Swiss cheese model applied to hospitals in The Netherlands, adapted from the theory of Reason and an illustration by Rose Wong [1]

There are several valid technical measures to evaluate processes in healthcare [6]. These measures are divided into two categories: Patient-reported experience measures (PREMs) and Patient-Reported outcome measures (PROMs). The first measures the subjective perceptions of patients and/or clinicians about the quality of care. The second evaluates healthcare outcomes by use of quality indicators [6]. Programs established to enhance the quality of care are evaluated and influence the quality of health positively [3]. In literature, the Aanschafdossier has been evaluated as part of VMS using healthcare outcomes, while a subjective perception measure relating to the patient's or clinician's experience is missing. The first category mentioned uses quality indicators 'potentially avoidable damage' and 'mortality rate' to evaluate the effect of the Aanschafdossier [18]. Both indicators lowered between 2004 and 2012 because of the introduction of VMS. However, there is no further decline noticeable since 2015 and 2016. Also, there is no decline noticeable in the percentage of avoidable injury and death due to medical technology in 2019 compared to 2015 and 2016. Another conclusion of the evaluation was that only a small number of files had an avoidable injury, only 0,5% of the avoidable injury that was caused by medical technology eventually contributed to death. The research concludes the overall failure of medical technology is low. Even though there is a reduction in the number of safety incidents, it is difficult to evaluate the effect of a specific intervention in the prevention of safety incidents using quality indicators. The multiple initiatives that target at prevention of safety incidents function as a total and confound each other. Therefore, it is difficult to evaluate one single action.

2.2 Actions to prevent safety incidents in hospitals

Numerous actions or innovations are executed by governments, health systems, citizens, patients, and health workers that together achieve the goal of high-quality care [15]. Next to the actions required in the Productdossier, which we will further elaborate on in Section 2.3, other actions are prescribed to prevent safety incidents. Examples of these actions are inspections, accreditation, protocols and guidelines, product measures and incident reporting, which will be briefly addressed in the following paragraphs. Each layer of defence intended on patient safety has advantages and disadvantages due to failures in safety incident prevention.

IGJ monitors the safety, quality, and accessibility of healthcare in the Netherlands via *inspections* [19]. IGJ develops and checks upon quality indicators, analyses incident reports, and calamities, and does research on risk-related themes. Also, they control whether hospitals fit the Covenant via inspections.

Accreditation is "the external peer review that evaluates a healthcare organization's compliance against pre-defined performance standards, with the ultimate aim to improve healthcare quality" [20]. Accreditation is a common strategic external quality assessment tool in healthcare wherein stakeholders reflects similarly to the Productdossier on different processes in a hospital. Evidence supports that accreditation positively impacts performance in a hospital setting [20].

Guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [21]. Protocols and guidelines are established to control processes and reduce variation and costs. The focus on protocols and guidelines sometimes has a negative effect, as the professional has fewer possibilities and capacity to focus on the healthcare that is needed for a particular patient or certain circumstance [13].

Several *product measures* are done to prevent safety incidents regarding the manual or design of a product [2]. For example, by limiting the number of parts of common equipment. This prevents harm, as the same product on a ward requires the same manual and usage. Also, standardizing work processes improves safety. Additional2ly, a design of a product can prevent safety issues.

Another method to prevent safety incidents or to detect their cause is to report, monitor and research incidents or unintended events [3]. This method is called *Veilig Incident Melden* (VIM) ('Safe Incident Reporting'). The monitoring of safety incidents leads to better performance [2]. However, incident

reporting is selective and incomplete [22]. Also, it is sometimes difficult, if not impossible, to determine and judge whether events were preventable, which makes it hard to research. Next to that, safety incidents that are not detected are not reported. The number of obliged incident reports via VIM in the Netherlands has lowered since 2017 [4]. In 2017, in total 1035 incidents were reported of which 7% had to do with equipment, material, and ICT. In 2021, 810 VIM records were reported, of which 6% had to do with equipment, material, and ICT [4].

Another measure that is used to prevent safety incidents is the *Aanschafdossier* ('Procurement File') as a result of the Covenant. At Isala, the term Aanschafdossier is used like in other hospitals, However, these probably differ over other hospitals in The Netherlands. We chose to use the Dutch terms for clearance and total covering of the content. The Covenant was established in 2011 and consists of a set of rules medical specialistic care has to comply with. Hospitals must document the selection of medical devices or a group of medical devices, called an Aanschafdossier. A fitting workflow concerning the introduction, usage, preventive- and corrective maintenance, evaluation, and rejection help to fit all requirements of the Covenant. The Aanschafdossier are seen as a framework to perform a set of actions before using a new product in the hospital. One of these actions is to create the *Productdossier* ('Product file') [7]. In the next section we discuss the components of the Productdossier.

2.3 Components of the Productdossier

The Productdossier consists of five components: need for the new product (1), product requirements document of the healthcare facility (2), risk analysis (3), competency requirements and corresponding education of future users and technologists (4) and a periodic evaluation plan (5). The original description of the components in Dutch and the shortened terms we use in the remainder of the report in figures and tables can be found in Appendix A. In the following paragraphs, we briefly explain the content of these components and the supporting literature.

The first component of the Productdossier is the *Need for the new product*. This describes why the product is needed in the hospital and why it is different compared to the other existing products in the assortment [7]. The goal of this component is to clarify the objective of purchasing the new product is clear and to prevent multiple unnecessary similar products. Limiting the number of kinds of common equipment prevents harm, as the same product on wards or hospital-wide requires the same manual and usage [2]. The "Specification of the need" is the first out of six steps in the *race car model* by Telgen

et. al that describes the purchasing process [23]. The specification phase has multiple dimensions, of which one is a product requirement which we will further elaborate on in the following paragraph.

The second component in the Productdossier is a *Product requirements document of the healthcare facility* [7]. This entails the requirements, behaviour, functionality and features a new product has to meet according to the healthcare facility [24]. Also, technical and physical attributes are described, or logistical requirements in terms of volume and delivery times are specified during this stage [23]. Proper specification of a product is crucial for the procurement of a product and can save most costs during the procurement of a product.

The third component of the Productdossier is a *Risk analysis* [7]. The risk analysis is used to identify, recognise and describe potential problems, to prevent safety issues [25]. The following seven risk management stages are identified regarding risk analysis: organizational context definition, risk identification, risk analysis, risk evaluation, risk treatment, monitoring and review, and communication and consultation. Risk management is important in healthcare, as this relates to complex and high-risk organizations. Risks can affect patients, personnel, costs and the hospital's reputation, therefore it is important to prevent safety incidents to happen. Some risks are acceptable when the benefits outweigh the drawbacks of the risk. A risk matrix is used to assess the likelihood, the consequence level and the risk rating. Also, it prioritizes risks that need to be addressed.

The fourth component in the Productdossier is describing the *Competency requirements and corresponding education of future users and technologists* [7]. This includes a check whether new education or instructions are needed, by checking the current competency requirements and the desired competency requirements. By the time a new healthcare provider finishes their initial educationthey are registered into the quality register *Beroepen in de Individuele Gezondheidszorg* (BIG) ('*Individual Healthcare Professions Act'*) [26]. This register documents whether a healthcare professional had the corresponding education. Afterwards, continuous education is a necessity for healthcare professionals to provide high-quality care, prevent safety issues and guarantee quality [27]. The healthcare industry is continuously evolving as described in Section 2.1, and so are health technologies. Education about new techniques and technologies leads to competent and skilled healthcare professionals. Research by Nivel [28] concludes that healthcare employees that perceive the quality of care as moderate or poor experience a higher need for further training. Education is given in the forms of lectures, symposia, training or e-learnings [27]. In some cases, an adjusted manual or instruction is enough.

The fifth and last component in the Productdossier is a *periodic evaluation plan* of the new product [7]. This information entails a plan for the periodic evaluation after commissioning the new product for a certain period of time. Evaluation is an essential part of quality improvement [29]. However, it is often considered to be complicated by tensions and friction between valuators, implementers and other stakeholders. Brewster et al. [29] did research towards the evaluation of safety in healthcare [29]. This research concludes that there are seven causes for failure: lack of shared understanding of the goals of the evaluation; confusion about roles; relationships and responsibilities; data burdens; issues of data flows and confidentiality; the discomforts of being studied and last the impact of disappointing or otherwise unwelcome results. In line with this research, preliminary research described in Appendix K shows that Isala lacks a periodic evaluation plan for medical technology and equipment. Therefore, we expect the functionality to be low and the compliance burden to be high. Preliminary research showed that one hospital has the option to evaluate certain new products after a certain period of time and that one gets an automatic reminder to do this.

The quality of the individual components of the Productdossier is important to enhance the quality of care in the patient safety domain. There is a literature gap in the effects and the quality of the specific components of the Productdossier, neither does the literature evaluate the effect or the quality Productdossier and the Aanschafdossier. These actions are difficult to evaluate, which is explained by the Swiss cheese model. Moreover, establishing a Productdossier is a time-consuming process, while the effects of the Productdossier are still not accounted for. The corresponding theory regarding functionality and administrative burden is called red tape. We will further elaborate on this in the next section.

2.4 Red tape

A theory that corresponds to the burden caused by rules and administration is the theory of *red tape* [1, 11, 12]. Healthcare professionals experience a high regulatory burden due to administration. Administration causes a high pressure, much time and a delay in the delivery of care [30]. The Productdossier can also be seen as a rule. Van Loon et. al [1] describe red tape as “rules that employees perceive as burdensome and not helpful in achieving the rules’ functional objective in their respective job”. Multiple authors recently described the negative effect of red tape on the performance of an organisation and the attitude of employees [10-12]. Employees experience a burden that arises due to administration in the form of excessive time or energy, complexity or because it is frustrating [1].

Tummers et al. [31] examined that red tape has a negative effect on citizen satisfaction. Due to red tape, employees have less autonomy to do their job.

Van Loon et. al [1] divide red tape into two dimensions: the compliance burden and the lack of functionality. This creates a quadrant, a two-dimensional job-centred red tape scale, as shown in Figure 2, which is used to detect the location and the severity of red tape. The horizontal axis is labelled as the *compliance burden*, which is the extent to which the rule or administration is seen as a burden due to excessive or unnecessary work pressure, amount of time, delay, frustration, energy, or other resources spent in executing a rule. *Lack of functionality* is indicated on the vertical axis and refers to a rule that does not achieve its intended aim. This creates four quadrants:

1. *Unnecessary rules:* Employees in this category think that rules and administration are useless. It does not help to improve the quality of healthcare. However, it does not cost them much time and effort to execute it, and it does not increase pressure.
2. *Red tape:* Employees in this category think that rules and administration are useless. It does not help to improve the quality of healthcare. Also, it costs much time and effort.
3. *High-quality rules:* Employees in this category see the importance of rules and administration. It is necessary to execute this to deliver high-quality care. At the same time, it does not cost them much time and effort to execute it, and neither does it increase pressure.
4. *Necessary bureaucracy:* Employees in this category see the importance of rules and administration. It is necessary to execute this to deliver high-quality care. At the same time, it costs them much time and effort to execute and pressure is increased.

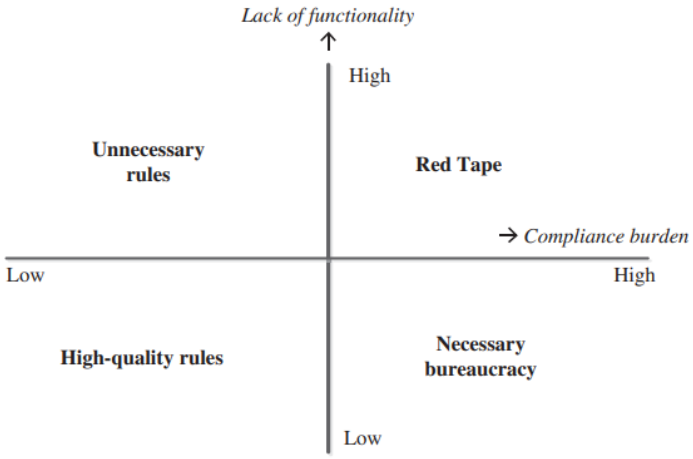


Figure 2 Red tape scale, derived from van Loon, Leisink, Knies and Brewer [1]

Van Loon et al. [10] address the lack of functionality and the compliance burden in 8 rules:

For lack of functionality:

- Have a clear function for my job activities
- Contribute to the goal of my job activities
- Help me do my job well
- Serve a useful goal

For compliance burden:

- Cause much pressure at work
- Take a lot of time to comply with
- Cause much delay
- Cause a lot of frustration

A whitepaper of healthcare insurer IZZ (Instituut Ziektekostenvoorziening Ziekenhuiswezen) evaluated the regulatory burden in healthcare upon the quadrant of Van Loon et. al [30]. They position healthcare workers in the quadrant of Van Loon et al. [1] 2,5% of the healthcare employees in the top left quadrant unnecessary rules [30]. 26,7% of the healthcare employees are in the top right quadrant of red tape. 21,6% of the healthcare employees are in the bottom left quadrant high-quality rules. 49,1% of the healthcare employees are in the bottom right quadrant necessary bureaucracy.

Frontline employees experience more red tape than managers [1]. Moving down the hierarchy, each level of management adds new layers of rules and regulations. To fully access the burden of a rule, it is important to address employees in different hierarchical layers of the organization. The type of job influences the extent to which functionality and compliance are experienced by employees. Tummers et al. [31] also describe when respondents have a better understanding of politics, the effect of red tape is weakened. They conclude that knowledge can buffer red tape effects on citizen satisfaction. This is in line with Van Loon et al. [1]. Therefore, we expect that managers experience less red tape than the other functions.

Even though red tape has been linked to healthcare in literature [30], there is no literature about the relation between the Productdossier and red tape. Ideally, the components of the Productdossier are positioned bottom left in the quadrant of van Loon et. al in high-quality rules: it adds value to the

healthcare, while simultaneously, the rule is not perceived as burdensome by employees. However, due to preliminary research, we value the general Productdossier in the quadrant necessary bureaucracy. We expect that the first four components are either received as high-quality rules or as necessary bureaucracy in the red tape scale. As we expect that there is no periodic evaluation plan as described in Section 2.3, we expect that components that are not in the system are perceived as red tape.

2.5 Conclusion of the literature study

Quality management in healthcare is important to ensure patient safety. Patient safety is a dimension of quality of care. To prevent safety incidents from occurring, multiple layers of defence are used, like the Aanschafdossier. However, even then safety incidents are occurring, which is explained by the Swiss cheese model. The Swiss cheese model addresses failures in layers of defence.

The Productdossier is divided into five components: need for the new product (1), product requirements document of the healthcare facility (2), risk analysis (3), competency requirements and corresponding education of future users and technologists (4) and a periodic evaluation plan (5). To what extent this patient safety initiative is an accurate tool to enhance patient safety has not been assessed yet in the literature. Also, this is difficult to examine because of the confounding effects of the other innovations. Quality indicators are not effective in the measurement of quality of care, as the multiple actions affect patient safety as described in the Swiss cheese model.

In this research, we use the red tape quadrant and the Van Loon et al. [1] to position the perception of employees on the Productdossier, for stakeholders of multiple layers of hierarchy. Red tape is described as "rules that employees perceive as burdensome and not helpful in achieving the rules' functional objective in their respective job". As both terms "lack of functionality" and "compliance burden" imply negative experiences and are biased, we decided to use the terms "functionality' and "compliance" in this research. We expect that different groups of functions have different opinions on the functionality and compliance of the components. Also, we expect that the components are valued differently.

The perception of employees on the effect of the Productdossier regarding patient safety has not been researched yet. To make a distinction between the perception of the specific parts of the Productdossier, the five components of the Productdossier are used. Figure 3 illustrates the set-up of this

research connecting the literature described in this research. The next chapter will address the strategies used for this research.

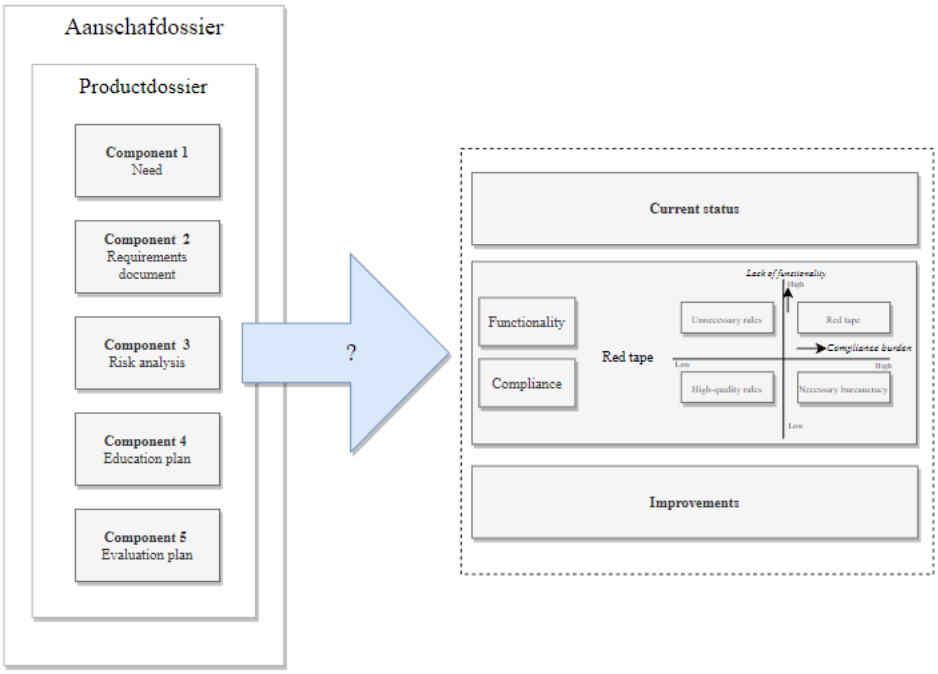


Figure 3 Research model

3. Methodology

This study uses a descriptive cross-sectional study design, by collecting qualitative and quantitative data through the use of semi-structured interviews. Interviews are a valuable instrument to generate new ideas for process improvement [6]. As there is no golden standard for Aanschafdossiers nor Productdossiers, benchmarking is not considered a relevant technique. Also, retrospective research that would compare the perception before the introduction of the Covenant is not possible, as the introduction already took place. Therefore, a descriptive cross-sectional study that interviews a set of subjects at one point in time best fits this research. Section 3.1 addresses the sampling and the study settings. In Section 3.2, we describe the construction of the interview guide. Section 3.3 describes the strategy for the data analysis.

3.1 Sampling

To provide a reliable answer to the research question, multiple hospitals are invited to participate in this research. The criteria we used for inviting hospitals was that it is an academic hospital or a top clinical hospital, and the hospital should produce more than 200 new Productdossiers annually, to make sure the respondents are experienced with the Productdossier. Isala and Máxima Medisch Centrum are the two hospitals that participate in this research. Both Máxima MC and Isala are united in a partnership with five other hospitals called “mProve”. This collaboration initiative is an innovative network that has the ambition to deliver better care and improve [32, 33]. This section further contains a case description of the two hospitals.

Isala, the hospital this research is commissioned by, experiences difficulties regarding compliance with the Covenant. Isala is one of the 27 top-clinical hospitals in the Netherlands. Isala is located in Zwolle, Meppel, Steenwijk, Heerde, and Kampen [32]. Zwolle and Meppel are the main locations. Isala provides care for 690,000 inhabitants in the region. Isala has 1,250 beds, and had 211,742 first outpatient visits. Isala uses the Aanschafdossier as a framework for ordering a new product. Therefore, Aanschafdossiers are created for every category of products. This results in approximately 1200 new Aanschafdossiers and thus Productdossiers annually. Characterizing the process of Isala, all applications follow the same entrance in the process which makes it more clear for the applicant. The final responsibility for Aanschafdossiers rests with the board of directors. The purchasing department of Isala is responsible for the Aanschafdossiers and Productdossiers of all new products purchased for the hospital, but a check on whether Productdossiers are complete is missing. The collection of files is called

"Aanschafdossier 2.0" and is documented in "Zenya": a quality- and risk management system [34]. Aanschafdossier 2.0 at Isala is evaluated in 2022 [8]. This evaluation highlights that the purchasing process is currently not efficient and does not completely fit the agreements of the Covenant. The entire process from application to usage of a new product requires much time, effort and dedication from a high number of employees of various disciplines.

Máxima Medisch Centrum (Máxima MC) is a second participant in this research. Máxima MC is located in Veldhoven and Eindhoven and is also one of the 27 top-clinical hospitals in the Netherlands [33]. Máxima MC has 560 beds and 422,360 first outpatient clinic visits annually. Máxima MC is currently improving the process for their Aanschafdossier and Productdossier. In their process, the hospital makes a distinction between investment products ("large" products that cost more than €10,000.-, including the purchasing and exploitation costs) and "*Commissie Beoordeling Medische Hulpmiddelen*" (CBMH) ("*Committee for assessment of medical devices*" in English) products ("small" medical products with a low cost). Annually, this results in about 450 new Productdossiers, of which about 50 dossiers are investments- and 450 dossiers are CBMH products. Characterizing the process, Máxima MC determines as much as possible at the beginning of the application what the implementation looks like and which stakeholders should be involved immediately from the start. The final responsibility for Aanschafdossiers rests with the board of directors. However, within the implementation, a combination of the representative of the board of directors, clinical physics and the purchasing department is responsible for the process of the Aanschafdossier. Within one Productdossier, the project leader is responsible for Productdossiers of investments and the applicant is responsible for Productdossiers of CBMH articles, which are checked by the investment committee or CBMH. The Productdossier is documented in Zenya as well, but the hospital will switch to the software of AFAS one month after the publication of this research. Máxima MC is currently improving its process to involve stakeholders in an earlier stage.

A list of roles regarding the process of the Productdossier at Isala is used as starting point to select a valuable set of respondents. This list and the description of the function can be found in Appendix B and is constructed with help of the contact person at Isala. Preliminary research on the Aanschafdossier at eight hospitals in the Netherlands shows that each hospital has a unique process. Consequently, each hospital has assigned tasks and responsibilities regarding the Productdossier to stakeholders with different job descriptions. To have a similar population at Isala and Máxima MC, this research identifies and describes the five roles at Isala to invite the corresponding person at Máxima MC. We choose to

invite stakeholders varying over different levels of hierarchy, since bureaucracy is experienced differently at different hierarchical levels as described in Section 2.4. Some roles have more executive power in the process of the Productdossier than others. Managers have more influence than purchasers. Likewise, process designers have more influence than applicants. The respondents are selected using a description of the roles regarding the process of the Productdossier at Isala. The five identified roles following the process of the Productdossier at Isala are the following: manager (1), process designer (2), product controller (3), purchaser (4) and applicant (5). Appendix B further elaborates on the definition of the function. These corresponding persons were assigned by the contact person of the hospital and invited by us.

During this research, we interviewed 11 respondents during 10 interviews; six from Isala and five from Máxima Medisch Centrum. Respondents 3 and 4 were interviewed during one session. Respondent 10 was added to the research population, as we noticed during the other interviews that the perspective of another employee might also bring relevant information. The interview with respondent 11 at the end of March is used to validate the conclusions of the research. The rest of the interviews took place within a time frame of one month, starting on the 23rd of January 2023. The list of respondents, their corresponding anonymous number, their function, the hospital they were working at, the duration of the interview and the number of pages of the transcript are shown in Table 1. Six of the interviews were face-to-face at Isala. Five respondents (respondents 1, 2, 3, 4 and 6), were interviewed on Microsoft Teams, an online communication tool. Both interviewer and respondent saw each other and talked to each other. During the physical interviews, flashcards were used with the five components, to make sure the respondent knew which component is discussed. Also, a scale on paper was given to the respondents to visually structure the interview. This has been left out during one interview, it indeed turned out that the interview was less structured. During the interviews on Microsoft Teams, we used PowerPoint to show the flashcards and the scale. The interviews have been transcribed with the program Amberscript.

Table 1 Sampling of respondents

Respondent number	Document-number in ATLAS.ti	Hospital	Function	Tasks relating to the pre-described function	Meeting	Length of transcript in page numbers	Interview duration [hh:mm:ss]
1	8	Isala	Teammanager Inkoop	Manager	Online	23	0:50:16
2	5	Máxima MC	Hoofdinkoop medisch	Manager	Online	23	0:56:03
3 & 4	7	Máxima MC Máxima MC	Biomedisch technoloog Functioneel beheerder afdeling inkoop	Product controller Process designer	Online	24	0:50:26
5	3	Isala	Assortimentscoördinator medische hulpmiddelen	Product controller	Face to face	22	0:48:39
6	4	Máxima MC	Coördinator medische hulpmiddelen	Product controller	Online	20	0:46:39
7	6	Isala	Kwaliteitsfunctionaris Medische Technologie en Beheerder domein Medisch Equipment	Product controller	Face to face	25	0:48:12
8	1	Isala	Junior Inkoper	Purchaser	Face to face	20	0:43:11
9	2	Isala	Decentraal assortimentsbeheerder operatiekamer (OK) (“operating room” in English)	Applicant	Face to face	20	0:45:12
10	9	Isala	Intensive Care (IC) verpleegkundige en decentraal assortimentsbeheerder (DAB'er) (Decentral inventory controller in English)	Applicant	Face to face	37	0:58:36
11	10	Máxima MC	Head CBMH, trauma surgeon	Applicant/ product controller	Online	7	0:18:58
					Total	214	7:46:12

3.2 Interview guide

The interview guide for the semi-structured interview is constructed according to the five steps described by Moser and Korstjens and is documented in Appendix C and Appendix D [35]. During the first step, the prerequisites to use a semi-structured interview are identified. Second, knowledge of the

literature review is used. Third, the interview guide is formulated by operationalizing the knowledge in the second step. Fourth, the pilot interview is tested. Fifth, the interview guide is completed using feedback from the fourth step. The initial interview guide is translated into Dutch in Appendix D which will be used during the interviews. The translations have been validated by another independent researcher.

The content of the interview guide consists of four parts. During the first part, the research is introduced by explaining the structure of the research, the definition of the Aanschafdossier and Productdossier, the five components and an explanation of functionality and compliance. During the second part, a few general questions are asked towards the background of the respondent and the association with the Productdossier. During the third part, the respondents are asked to evaluate a set of four questions for each of the five components. The first question asks about the current status of the component. The second question asks towards the functionality of the component. The third question asks towards the compliance of the component. The second and third question are based on Van Loon et al. [1] about red tape. The respondents are asked to rate the components on functionality and compliance on a scale of one to five, according to the Likert scale [36], and to explain their answer. The explanation for their valued scale is considered as most important during the analysis. This is repeated for the other components. During the fourth part, a few closing questions are asked to verify the scale of the respondent. Also, the respondent is asked if there was information missing that is relevant.

3.3 Analyses

The transcripts have been coded in the program ATLAS.ti, using a hybrid coding strategy of inductive and deductive thematic analysis. This is similar to the approach described by Fereday and Muir-Cochrane [37]. This research describes six stages, of which we used the first, fourth, fifth, and sixth stages to structure our analysis.

During the first stage, the coding manual is developed using literature and the process of the Productdossier [37]. Also, the codebook is constructed using the structure of the interview questions: the five components, the four topics current status, functionality, compliance and improvements, and last whether what the respondent mentioned was *positive*, *negative*, or *neutral*. This is derived from sentiment analysis [38]. This is useful for the sixth stage in which results are obtained. To check the opinion of the respondent, a multipoint scale is used using 5 points to describe compliance and functionality. To the value of *positive*, *negative* or *neutral*, *general* is added. Next to that, the

stakeholders and steps in the process have been used as code. In the codes, a distinction between Isala and Máxima MC is made. The codebook of codes consists of 218 codes. A partial list of codes is documented in Appendix F, the rest is available on request with one of the researchers.

During the fourth stage, the initial codebook is applied to the transcripts to identify meaningful units of text using the template analytic technique [37]. During the process, 32 codes emerged directly from the data using inductive coding, in case phrases were relevant but did not fall into the pre-defined codes. In total, the codebook consists of 250 codes. The codes that were added during inductive coding are indicated with a bullet point in the codebook in Appendix F. The list of codes is connected to groups and folders, to structure the codes logically. The groups of the codes can also be found in Appendix F: Coding The first four interviews have been coded three times, the rest is coded twice until code saturation is reached [39]. In total, 1,661 quotations are coded.

During the fifth stage, the codes are connected and themes are identified. This has been done using the tool “Code-Document Analysis” in ATLAS.ti to open the phrases according to the groups that have been entered while importing the preliminary codebook into the program. The 32 codes emerging from inductive coding are attached to groups as well by identifying themes.

During the sixth stage, themes were further clustered to connect overlapping themes that are relevant for analysis. This is done using thematic analysis as explained in [40]. This strategy is considered to be useful for health and well-being research [41]. The thematic analysis is structured using the three sentiment analysis components derived from Devika et al. [38]: positive, negative, and neutral. We added general to this threefold. For example, the opinion about the compliance of a respondent on a specific component has been identified. In this way, the interaction between texts is identified. An example of how this looks like in ATLAS.ti is shown in Appendix G. From there, results are described, by summarising quotes per respondent.

This research includes ethical considerations, as the study involves human subjects during interviews. The study is approved by the Ethics committee of Behavioural, management and Social Sciences/ Domain Humanities & Social Sciences of the University of Twente. The registration number is 230002. The invitation for the interviews is accompanied by an informed consent letter in Appendix E, which was issued before the interviews. If this was not granted, no interview would have taken place. However, all respondents agreed. The data is stored safely. The names of the respondents are anonymised.

4. Results

In this chapter, we discuss the results following from our research. In Section 4.1, we discuss the general results of the research, where we address general functionality, general compliance burden and the results of the scale. In Section 4.2, we perform a cross-case analysis of the results following from the interviews. Also, we discuss the results derived from the different functions of the respondents. In Section 4.3, we discuss the results per component. In Section 4.5, we discuss ideas generated for improvements. There are several quotes used to support the results, these are translated into English. The original quotes are shown in Appendix I.

4.1 General results

In general, all respondents suggested that the Productdossier is *functional* in enhancing patient safety. A quote of respondent 5 that supports this is “I think it really contributes to the safe usage of medical equipment a lot.”. The Productdossier is considered functional, as it forces the stakeholders to think of aspects that influence patient safety before introducing a new product. However, there are three caveats mentioned. First, respondents 8 and 10 both mentioned that a Productdossier is more functional for medical equipment than for facility products. Respondents make a clear distinction in the nature of the products regarding costs and risks. Second, respondent 2 reports that most incidents occur because of human failure and mistakes. This is important to acknowledge, as multiple factors confound patient safety. Third, while it is considered as important to think it through, the emphasis on documenting in a Productdossier is questionable. Respondent 4 mentions that a balance should be found between compliance and functionality.

In general, the majority of the respondents agree that the experienced *compliance burden* of the Productdossier is high. Respondents 1, 2, 4, 5, 7 and 10 directly state this during the interview. For example, respondent 8 claims: “We created a monster.”. This view is echoed by respondent 5, who quoted for backorders: “Our file is long-winded.”. Respondents 5 and 8 mention that the compliance burden is expected to be higher for applicants that do not apply for new products often. Respondents 4, 5 and 10 agree that every component should be thoroughly thought out, but that documenting this in a file is not always necessary and should be easier to comply with. Respondent 10 wonders “So sometimes, you feel like, is this deemed to be necessary?”. Respondent 4 claims the documenting of Productdossiers is too much: "I appreciate laws and rules. This is what the rules prescribe, and I know what we need to do. But sometimes it is so much, sometimes it overshoots the mark. And then, it raises

frustration, and people start to use the back door." There are a lot of processes and procedures, which makes it difficult for employees to work with. This can be explained by the complexity of hospital systems, which is also addressed in the literature review [2]. The systems used for the processes do not support the work of the employees, as Zenya is sometimes slow and not useful. Respondent 1 states "When you look at the easiness, we have created a paper tiger. That creates an impressive administrative burden for hospitals".

During the interviews, we asked the respondents to fill in a *scale* for compliance and functionality towards the components. The results per respondent are documented in Appendix H. The averages per function are given in Table 3. In general, there is a consensus between the answers given during the interviews and the scores given in the scales. In Results per component4.3, we discuss the average scores per component to reflect on the answers given during the interview. There are a few things noticeable when looking at the scores per respondent. Multiple respondents did not give a score to specific components, as they for example did not experience a burden themselves or did not feel the right person to judge about this. This can be explained by the different functions and roles as given in Appendix B: Roles Of Stakeholders Of The Aanschafdossier; not every respondent is involved in all process steps. Respondent 3 did not assign any scores due to a lack of knowledge on the Productdossiers. Interestingly, respondent 4 made a distinction in scores for products at high risk or high costs. We further discuss this in Section 5.1. We calculated the averages per component and respondent. If respondents gave scores between two numbers, the average has been used to calculate the total averages. In general, we see that the numbers comply with the answers given. We noticed that the numbers of respondent 7 did not comply with the answers they gave: the numbers they gave regarding compliance were from his job position instead of from an overall perspective. Also, we noticed that multiple respondents confused the definition of functionality regarding patient safety with overall functionality. Even though we explained this multiple times, we noticed this term was still misinterpret sometimes. Therefore, the validity of these questions is low. On the other hand, this might also be an interesting finding that respondents find it difficult to disconnect functionality towards patient safety separate from other ways of functionality, for example to the organisation. However, still we take the scales into account but do not conclude solely on this scale.

To *summarise* the general results, the documentation in the Productdossier is perceived as functional. The compliance burden is high. This is in line with the results retrieved from the scales.

4.2 Cross-case analysis

We did a cross-case analysis to analyse the results combined. Table 3 displays the respondents' perception of the Productdossier components in the red tape scale. The results of respondent 3 are missing as they did not give answers to the related questions. The highest density for the first component is unnecessary rules, with a density of 6. This means, the lack of functionality is experienced as high while the compliance burden is low. However, the difference compared to the other parts of the quadrant is small. Therefore, it is difficult to position this component. The highest density for the second, third, fourth and fifth components is necessary bureaucracy, with a density of 6, 7, 7, and 6 respectively. This means the compliance burden is high and meanwhile lack of functionality is low. For the fourth component high-quality rules also received a density of 7. Note that for component five the density scores on red tape and high-quality rules are close (both 5). This means it difficult to draw a conclusion. In the last column, the density is given as a percentage of the total amount per component. In Section 4.4 we visualise the results to the components in the red tape scale and we interpret the results..

Table 2 Cross-case analysis of the results

Component	Quadrant	Respondents									Density	Procentual density
		A: Managers		B: Process designer	C: Product controller			D: Purchaser	E: Applicant			
		1	2	4	5	6	7	8	9	10		
1. Need	Red tape	●	●	●	●	●					5	25%
	Necessary bureaucracy			●				●	●	●	4	20%
	High-quality rules			●			●	●	●	●	5	25%
	Unnecessary rules	●	●	●	●	●	●				6	30%
2. Requirements document	Red tape		●					●			2	20%
	Necessary bureaucracy	●		●	●	●	●			●	6	60%
	High-quality rules				●		●				2	20%
	Unnecessary rules										0	0%
3. Risk analysis	Red tape									●	1	8%
	Necessary bureaucracy	●	●	●			●	●	●	●	7	58%
	High-quality rules				●	●	●	●			4	33%
	Unnecessary rules										0	0%
4. Education plan	Red tape			●							1	6%
	Necessary bureaucracy	●	●	●		●	●		●	●	7	41%
	High-quality rules		●	●	●	●	●	●	●		7	41%
	Unnecessary rules			●	●						2	12%
5. Evaluation plan	Red tape			●		●		●	●	●	5	26%
	Necessary bureaucracy	●	●		●	●	●	●			6	32%
	High-quality rules	●			●	●	●	●			5	26%
	Unnecessary rules					●		●	●		3	16%

Legend

	Respondent from Isala
	Respondent from Máxima MC
●	During the interview, this is at least once implied by the respondent
Density	Total number of times this is at least once implied by the respondent
	Density of 0, 1 or 2
	Density of 3, 4, or 5
	Density of 6, 7, 8, or 9
Procentual density	Density divided by the total density per component

Table 3 Average scores of scales on functionality and compliance per function

	Component	A: Managers (n=2)	B: Process designers (n=1)	C: Product controllers (n=3)	D: Purchasers (n=1)	E: Applicants (n=2)	Average of all functions
Functionality	**1: Need**	4.5	4	4	5	5	4.5
	2: Requirements document	4.5	5 | 2	4.7	2.5	4	4.1 | 3.5
	3: Risk analysis	5	5 | 3	4.7	4	4.5	4.6 | 4.2
	4: Education plan	5	3	4.3	4	4.5	4.2
	5: Evaluation plan	4	2	3.7	2	2	2.7
	Average	4.6	3.8 | 2.8	4.3	3.8	3.9	4.1
Compliance	**1: Need**	2	3	3.0	2	4	2.8
	2: Requirements document	4.5	3.5 | 4.5	2.3	4	4	3.7 | 3.9
	3: Risk analysis	4	5 | 4	1.5	3	3.5	3.4 | 3.2
	4: Education plan	3.5	3	1.7	3	3.5	2.9
	5: Evaluation plan	4	4.5	2.3	4	2.5	3.2
	Average	3.6	3.8 | 3.8	2.3	3.2	3.4	3.2

Table 4 Division in assigning quadrants of red tape scale assigned per function of the respondents

Average times assigned to a component				
Functions	**Red tape**	**Necessary bureaucracy**	**High-quality rules**	**Unnecessary rules**
Managers	1	3.5	1	1
Process designer	3	4	2	2
Product controller	1	3	4	1.67
Purchaser	2	3	4	1
Applicant	1.5	3.5	1.5	0.5

Table 4 provides an overview of the average times a dimension of the quadrant is assigned per function. This table is derived from the cross-analysis in Table 2. For example, the dots in the table show that the two managers together assigned the quadrant red tape to the five components twice. Therefore, in Table 4, the *average* number of times red tape is assigned to a component is 1. The 0.5 is the effect of calculating averages.

What stands out is that all of the respondents experience either perceive the most necessary bureaucracy or high-quality rules. This means that the functionality is perceived to be high, while the compliance burden is diverging. Also, we noticed differences per function when looking at the functions which places components in specific dimensions. Table 4 shows that the process designer assigned most components to red tape. That could be explained by the nature of their work, as these stakeholders feel responsible for the Productdossier. Necessary bureaucracy is also most often experienced by the process designer. Both product controller and purchaser assigned on average most times high-quality rules to the components. Last, the process designer assigned most often unnecessary rules to the components.

4.3 Results per component

In this section, we describe the results per component. In Table 6, we summarise the results. Afterwards, we describe per component the current status, functionality and compliance burden. In the end, we summarise the main result of that component and compare it to the scores given in Appendix H.

Table 5 Summary of the conclusion of functionality and compliance of the Productdossier

Component of the Productdossier	Functionality	Compliance burden
1: Need	Low	High
2: Requirements document	Low	High
3: Risk analysis	High	High
4: Education plan	Low	Average
5: Evaluation plan	Low	Average
Productdossier in general	High	High

Component 1: Need for the new product

Currently, 7 of the 9 respondents opined that the need for the new product is not documented well right now. The reason why this is not done well is because of the variety of reasons to purchase a new article. Another reason is because of the high number of applicants and therefore the quality varies a lot. The two other respondents mention that it is difficult for them to judge whether the description is a good explanation or not and feel they are not the right person to evaluate this. Still, they think it is important that this is documented well and that stakeholders are critical. This step helps the applicant and the user to thoroughly think through what is needed and why, and also prevents unnecessary products in the hospital. It should not take that much time.

Regarding *functionality*, describing the need for the new product is considered as important. However, none of the respondents mentions that this is crucial or directly contributes to patient safety. Respondent 4 comments "It forces people to wrap their brain about the product they want. In case that is not clear, that will come to attention. (…) Will it become unsafer when you do not document this? Probably not.". Respondents mention it is function for the organisation in other ways, for example to prevent "a proliferation of new products within this hospital" (respondent 1)), time and financial resources.

Whilst the *compliance* burden of this component should be low according to respondents 1, 2, 5, 6 and 8, many respondents agreed that it is currently experienced to be burdensome: "It is burdensome for people, we notice that, as it not performed well.", respondent 8 says. As a result of insufficient documentation, it creates a higher burden for the stakeholders further on in the process. Several respondents indicated that the compliance burden is depending on the applicant, as they are most occupied with this component. Also, content may be sufficient for one person and unclear for another as a result of different perspectives, roles of stakeholders and tasks, causing a difference in compliance burden. However, when asked about the compliance burden of this component related to other components, several respondents share the view that this component is relatively easy to comply with.

To *summarise* the outcomes of this component, the functionality to patient safety is low and so is the compliance burden. When looking at the *scales* filled in during the interviews, the compliance burden scores high. This could be explained by the fact that it is currently not performed well, therefore respondents said the compliance burden is high. The average scores given for functionality meet the answers given during the interview.

Component 2: Product requirements document of the healthcare facility

Currently, this component is used in both hospitals to specify which product is needed and which properties a product needs. Respondent 5 does not always see a product requirements document included. Respondent 7 is frustrated that applicants often already know which product they want, even though this could be done with help of this component. Respondent 1 wants to rely to a higher extent on suppliers; they have most knowledge of their products and sometimes know things that users do not know. At Máxima MC, two out of three respondents are positive about this component and one is negative. The respondent that is negative about the current status says that the product requirements document is done well for investments, but not for CBMH equipment. However, this respondent also mentions this is not always needed.

All respondents mention that it is important and *functional* to make a product requirements document. Respondents 4, 5, 6, 7, and 10 mention that it directly relates to patient safety. However, respondent 8 mentions that "I think it is a good call to have a few requirements, however, it would be better to consider the goal. I am looking for something for research, or something, or it could be smaller. A very comprehensive product requirements document does not increase quality for the patient. So, it can be smaller, easier, and it is not always necessary.". Other respondents share the view that this is not always needed, as it does not increase quality for the patient. Also, respondent 1 mentions that it is "false security", as the user could mention product requirements that are not right or missing. A few respondents mention that it is more important for products of high value or products of high risk.

The *compliance* burden of this component is high, and all respondents agree upon that. Almost all codes that are given by the respondents are valued as negative; the positive ones do not experience a burden in general towards this component. Respondent 8 says: "That takes up a lot of time.". Particularly, it costs time to do it right.

To *summarise* the results, making a product requirements document for the healthcare facility is important for the organization but does not directly lead to patient safety. The compliance burden of the component is high. When looking at the *scales*, the average functionality is valued as high. This also is in line with the summary: respondents assigned high numbers for functionality, as they value it as functional for the organization. The average compliance burden is high.

Component 3: Risk analysis

Currently, 8 out of the 9 respondents opine that the risk analysis is going well. The risk analysis is done based on the level of risk. It is questionable whether the system of ranking the risk according to "American Society for Hospital Engineering" (ASHE) questions are still valid. Others consider the risk analysis as a valid instrument to detect risks and to involve all important stakeholders. Respondent 4 sometimes makes a risk analysis even though this is unnecessary, diverging from the initial advise. Respondent 1 is negative about the current status and mentions that the content should be improved and "rest risk" (respondent 1) and results should be considered better. Another respondent mentions that asking the right questions during such an analysis is important, same as having the right person in the lead of the risk analysis.

When the respondents were asked about *functionality* of this component, all respondents agreed that it is "very *functional*" (respondent 9), a "useful component" (respondent 9) and that "it contributes a lot to the quality of care" (respondent 7). It makes people aware of the impact of products. Without this component, "regarding patient safety, it can harm patients" respondent 1 says. All codes attached to the phrases during the analysis in the interviews are either positive or neutral about functionality. Respondent 1 answers the question whether it contributes to patient safety with: "Absolutely. At the moment you introduce new products, you have to know what the possible risks are at the introduction of this product and which measures you have to take to reduce these risks." Interestingly, respondent 4 clearly makes a distinction in the risk and costs of products to the extent of functionality.

The *compliance* burden for this component is high, "I think that it takes quite a lot of time.' respondent 2 says. Respondent 7 says "The most work of the PRI is that you have to gather up with all stakeholders" and that "everyone wants to have a finger in the pie". Respondent 8 says that "It is a lot to ask of an employee.". A sidenote: respondent 2, 8 and 7 directly mention that it does not create a burden for them, but does for the persons who are involved during the risk analysis.

To *summarise* the results, performing a risk analysis is perceived to be very important for patient safety enhancement. Meanwhile, the compliance burden is expected to be high for the stakeholders involved. When looking at the *scales*, the scores given suit the answers given during the interviews. The average functionality and compliance burden is both high.

Component 4: Competency requirements and corresponding education of future users and technologists

Surprisingly, there is a lot of uncertainty in the *current status* of component 4. 8 out of 9 respondents do not know whether this is documented in the right way and whether education is given to the users. Only respondent 10, who is working as a nurse, responds that this process is going well. Education is recorded in a sort of passport, that shows whether a user is authorised and competent to use a specific product. However, there is no link to this in the Productdossier, which probably explains the uncertainty of the 8 respondents. Respondent 1 states that this is a lack of the Productdossier. Many respondents mention that it is unclear who is responsible for the content of this component.

Respondents say that education is *functional* relating to patient safety, as "it forces employees, applicants and wards to be conscious about education". Respondent 9 says: "very functional, very important. Yes, yes, it is really important that people are educated well.". Respondents also mention that healthcare workers feel responsible themselves as well. Respondent 7 mentions "but all the applications that are done, it never pans out". Also, respondent 1 is not satisfied with the way education is registered. Therefore, in order to keep the functionality towards patient safety as desired, one should make sure the education plan should be really executed.

The opinions about the *compliance* burden on the education plan are diverging. This could be explained by the following quote of respondent 7: "It is business as usual, it should be a piece of cake for them, but that costs time and effort." Most respondents involved in this research do not experience a high burden themselves. They claim that it should not cost much effort to write down the plan in the Productdossier, whilst complying with the educational plan and making sure new employees also learn skills is more effort taking. According to respondent 10, this is depending on the type of product.

To *summarise* the results, the education is functional to increase patient safety, however, documenting the education plan in the Productdossier is currently not experienced as improving patient safety. The compliance burden varies. When looking at the scores given in the *scales*, the averages match this summary. The compliance burden is experienced as average and the functionality is high.

Component 5: Periodic evaluation plan

Currently, all participants agree there is no periodic evaluation plan for products included in the process of the Aanschafdossier. Nevertheless, sometimes evaluations are scheduled for new products or trials. Respondent 6 states that Máxima MC has a mandatory evaluation for trials, and also mentions that feedback received about products is communicated to the supplier. Also, respondents mention that if something is wrong, they will get to know this anyways. During the interviews, questions arose regarding the term 'periodic'.

The current evaluations do not contribute to *functionality* towards patient safety. Interestingly, 7 out of 9 respondents (respondents 1, 2, 5, 6, 7, 8 and 9) say that it would be important to evaluate products. The remaining two respondents comment that it is only necessary for high-risk products or trials. The same 7 out of 9 respondents agree that something should change in the process, especially for certain products. Respondents 6 and 4 claim that it is important to evaluate trial products, but this is already included in the process at Máxima MC; the hospital where both respondents work at. However, "Does it contribute to functionality of patient safety? Individually, I think not.", respondent 4 sais. Surprisingly, none of the respondents directly links this to patient safety. Respondent 8 says "for the patient to a lower extent, but I think it is fundamental for an employee." Respondent 4 mentions that it could be functional to evaluate groups of products.

People do not experience *compliance burden* themselves in a periodic evaluation plan, as this is not performed. The opinion of respondents on the expected compliance burden when there would be a periodic evaluation plan is spread. Respondent 1, 4, 8 and 9 think this would be too much time taking to evaluate all products. On the other hand, respondent 2 mentions that it would cost time to design the process, but that evaluating itself should not take that much time. Especially "if you ruminate about which functions you need to group together, and one person of each function, then you can finish up the evaluation within half an hour till one hour." respondent 7 says. However, "The complexity can be found in the actions that need to be taken that follow from the evaluation plan." (respondent 7) and one has to keep this in mind. Respondent 4 says the "product differs on content". Therefore, the experienced compliance burden would be average.

To *summarise* the results, there is currently no evaluation plan. Most respondents agree that they would like to change something in this process. However, none of the respondents directly link an periodic evaluation plan to patient safety. This could be explained by the high compliance burden being expected. The idea of compliance burden on this component is divided among the respondents. When looking at the averages retrieved from the *scales*, the functionality is expected to be high and so is the

compliance burden. The high scores given to functionality can be explained by the fact that the respondents think this is functional for the organization. A high compliance burden can be explained due to all processes that need to change.

4.4 Results related to the red tape scale

When looking at the results in Section 4.2 and Section 4.3, the results can be placed in the red tape scale of Van Loon et al. [1]. This is done in Figure 5 and Figure 4. It is important to acknowledge that this model solely is based on functionality regarding patient safety. In Figure 5, we placed the components in the scale according to the result derived from conclusions in Section 4.3 using the results in Table 5. The perception of the compliance burden of components 4 and 5 was diverging. Therefore, we placed them in between unnecessary rules and red tape. Figure 4 is derived from the cross-case analysis in Section 4.2. The positioning is derived from the density scores. In general, this research concludes that the Productdossier contributes to patient safety enhancement and has a high compliance burden. Therefore, the Productdossier as a total is placed in the dimension necessary bureaucracy in the red tape scale by Van Loon et. al [1]. This is in line with our hypothesis given in Section 2.4.

In the literature review in Section 2.4, we described that we expected that the first four components would be in the high-quality rules or necessary bureaucracy in the red tape scale and the fifth to be in the red tape quadrant. When looking at the results of the quadrants, the results do not fully meet our hypotheses. When looking at , none of the components is placed in the high-quality quadrant. This can be explained by a high compliance burden. Only component 3 is in necessary bureaucracy, similar to the general Productdossier. Component 1 is placed in the unnecessary rules quadrant, component 2 is placed in the red tape quadrant, component 3 is placed in the necessary bureaucracy quadrant and components 4 and 5 are in between unnecessary rules and red tape, due to an average compliance burden. When looking at Figure 4, component 4 is also partly in high quality rules. Component 2, 3, and 5 are positioned in necessary bureaucracy, and component 1 is places in the unnecessary rules quadrant.

As described in Section 2.4, we expected that some functions would experience a different attitude towards the components. However, as of the ambiguous answers and cross-analysing strategy, we cannot base proper conclusions upon the attitudes of different stakeholders of the components. Therefore, this research cannot conclude whether one specific group experiences red tape to a higher extent than another group.

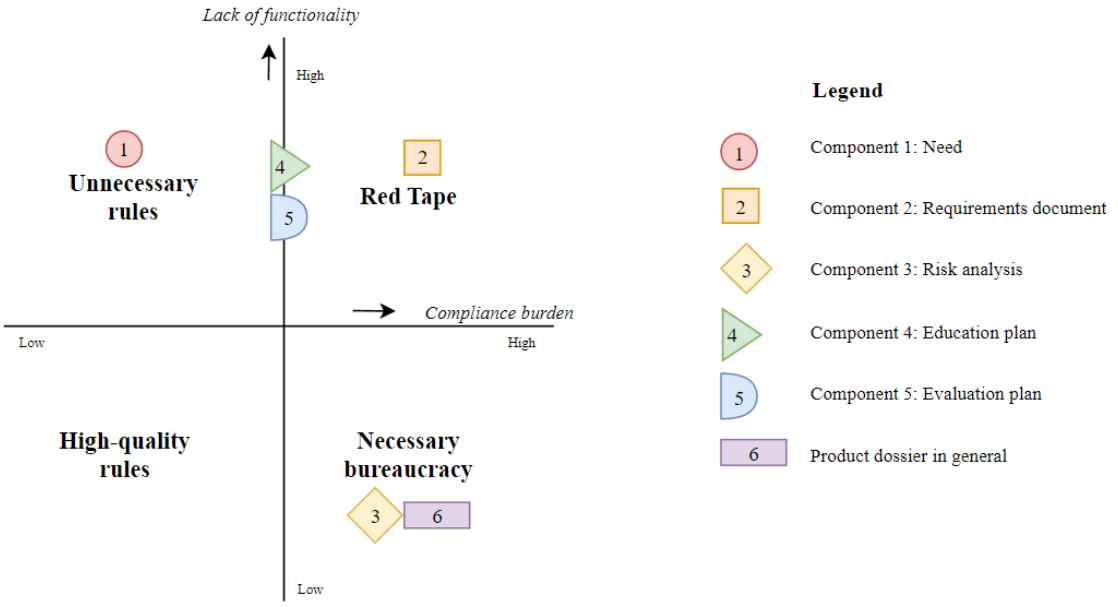
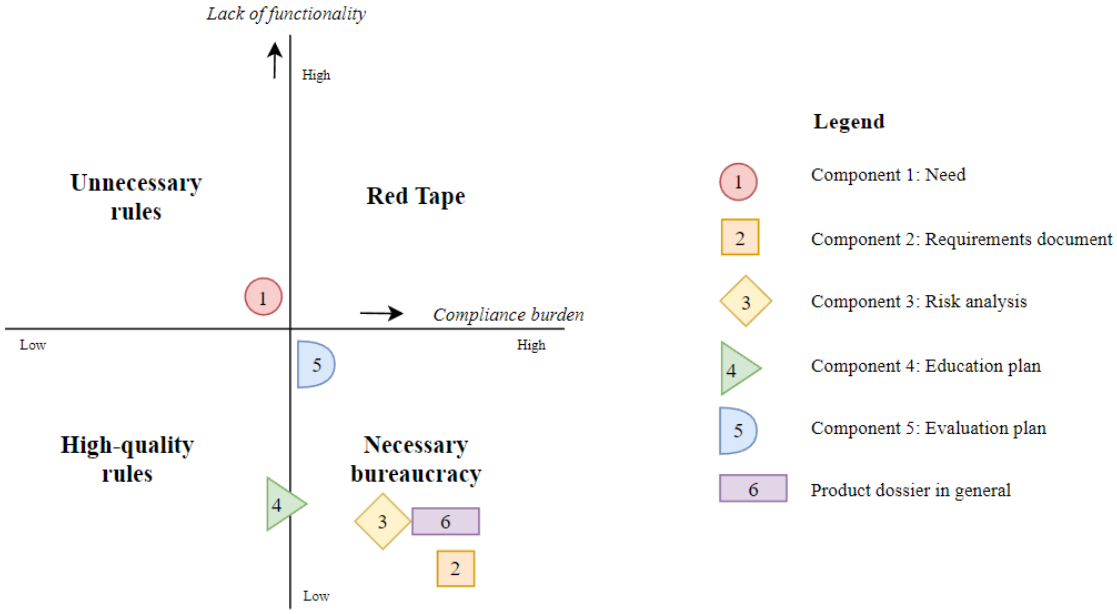


Figure 5 Positioning the components in the red tape scale according to the overall results



4.5 Improvements

During the interviews, all respondents generated improvements for the general Productdossier and its process, and for the components. Table 6 consists of a list of 43 improvements, divided per component. The high number of improvements given can be explained by the dissatisfaction we noticed during our research by the respondents.

Table 6 Suggestions for improvements derived from the interviews

Component	Number	Improvement suggestions
1: Need	1	Keep the content of this component short and simple.
	2	Discuss this component in an early stage. Paste copy the information discussed during an earlier meeting if possible.
	3	Make sure the applicant asks about the content of this component to the person who wants to use the product.
	4	Make sure the right summary is attached to the reason why a product is needed. This can be done using an easily accessible drop-down menu in the system. This data can be relevant later to sort reasons why people need new products. This could be valuable to analyse to later improve the process.
	5	Better guide people through the process using a format.
	6	Increase awareness of the functionality of this component. Make sure people do not see this as a way how to get the product or to receive a ref. number.
2: Requirements document	7	Make the product requirements document smaller and easier to fill in.
	8	Take a look at the product requirement documents of comparable products or the ones made in the past.
	9	Search for collaborations with other hospitals in product requirements documents and adapt them to your hospital.
	10	Ask for the input of the supplier. Make use of the knowledge and expertise of the supplier.
	11	Especially at Máxima MC: improve the excel file to make it easier for the user.
	12	Make a template for the content of this component.
	13	Take a look at value-based procurement and best-value approach for purchasing.
3: Risk analyis	14	Check whether the right persons are leading the risk analysis and whether that person asks the right questions during the meetings. Also, make sure that the right persons are involved, especially the user is important.
	15	Ask more questions to the applicant during the specification phase to make sure this component is easier.
	16	Take a look at whether AOC coding and ASHE questions still fit the products nowadays. Especially for technology or maintenance, this is questionable.
	17	Focus on the residual risk during the risk analysis. Discuss whether that risk is acceptable and how the rest risk can be reduced or controlled.
4: Education plan	18	Discuss with stakeholders who have the responsibility of the right education for users and the content in the Productdossier. Include both learning institutes in this process. Improve the collaboration between stakeholders on this subject and make sure there is more clearance.
	19	Applicants should be aware of the responsibility they have for education and being authorized and competent.
	20	Make sure the knowledge and expertise of the supplier are used in the education plan.
	21	Add a list to the Productdossier, or either a link to where one can find this, which users had the training and that they are competent and licensed.
5: Evaluation plan	22	Start performing evaluations and design a process for this. At the starting point, do this for selected products, for example, based on the costs of the product, the risk a product entails or across a group of products. Already mention during purchasing what would like to evaluate after a certain period.
	23	Design a template for how to evaluate products.
	24	Think of KPIs (Key Performance Indicators) in how to measure products.
	25	Take a look at the process for risk analysis and use that as starting point for the process for the evaluation plan. Stakeholders should be brought together and can prepare the evaluation beforehand, similar to risk analysis.
	26	Keep in mind during the process creation that from evaluations also desired adaptions arise. This also has to be included in the process to finish the PDCA cycle.
	27	Make someone responsible for the evaluation of a specific product. Till then, the file can not be closed.
	28	Check at least once a year what the assortment is, how often it is used and whether the value is correct.
General	29	Think about who can apply for a new product. There are a lot of applicants at both Isala and Máxima MC. It could be valuable to reduce this number to improve the quality. This could be done by combining similar departments or by increasing the usage of committees or groups of employees that discuss new products. On the other hand, it might also be relevant to have applicants that also use the products. A balance between the quality of documentation and the number of applicants has to be found.
	30	Make sure only qualified people apply for new products. Train them in the right way how to apply for a new product, the process, the content and the importance of the Productdossier.
	31	Make employees in the hospital more familiar with the process, expected and desired content and the value of the Aanschafdossier.

	32	Guide the applicants through the system. This could be done with help of a platform. This could be hospital-wide or nationwide. The platform could give tools on what to think of, how to apply for the product and how other wards or hospitals think of this product. Also, a few persons in the organisation could be assigned to help applicants that have questions about the process.
	33	Make sure there is better control over which products are purchased for the hospital and how each of the components is documented.
	34	Make sure the right stakeholders are involved in the early stage of the process. Currently, in the system, one can assign someone automatically to the process, but employees should make sure those stakeholders are involved and that it is not an (automatic) formality.
	35	Make sure the right steps are taken at the right moment in time.
	36	Find collaboration with other hospitals in The Netherlands. Sharing the results of evaluations could help other hospitals to purchase a product or avoid safety incidents. Also, the risk analyses could be shared. It has to be adapted to another setting, but the analysis of basic risks or results of the analysis could save time and effort.
	37	The Covenant is broad and does not provide tools for how to structure the process. Ask for more clearance in version 3.0 of the Covenant, ask the Inspection for help and/or make a defined plan at the hospital (or in cooperation with other hospitals) for what the content should fit. Make sure the mission and vision are clear upon this.
	38	Make conscious decisions for which products to start a Productdossier and what needs to be documented. For example, if it is medical equipment, a Productdossier needs to be made and then components A, B, C and D are necessary to fill.
	39	Think about disconnecting the Productdossier and the Aanschafdossier.
	40	Reduce the complexity of Aanschafdossiers. Think of a way that the content is specified enough to meet the Covenant.
	41	Make the required documents during the process mandatory. This could save time for employees that are controlling the products at a later stage.
	42	Clearly define the terms used for applicants regarding the Productdossier. For example “proefplaatsingen”, “zichtzendingen”, “bruikleen kort” and “bruikleen lang”, but also whether something is medical equipment or not.
	43	The introduction of another system might help to work better and more efficiently. The system should support the process and its stakeholders.

This list has been verified with three stakeholders of the Productdossier at Isala. Respondent 1, respondent 7 and an independent employee that has the same function as respondent 5 (productcontroller) ranked the idea for improvement according to the impact and effort matrix [42]; a tool for prioritising suggestions for improvement. We asked to score the ideas on impact (0-5) and effort (0-5). This results in the list in Appendix J. We calculated the averages of the three stakeholders. After that, we put this into the impact effort matrix in Figure 6.

Figure 6 Impact effort matrix on improvement ideas

A lot of ideas are high effort but also have a high impact. The following five improvements have been considered to be most promising, when identifying the quick wins with a high impact but a low effort in the impact effort matrix:

1. Keep the content of this component (component 1: need) short and simple.
2. Make sure the applicant asks about the content of this component (component 1: need) to the person who wants to use the product.
3. Make sure the right summary is attached to the reason why a product is needed. This can be done using an easily accessible drop-down menu in the system. This data can be relevant later to sort reasons why people need new products. This could be valuable to analyse to later improve the process.
4. Take a look at value-based procurement and best-value approach for purchasing.
5. Clearly define the terms used for applicants regarding the Productdossier. For example “proefplaatsingen”, “zichtzendingen”, “bruikleen kort” and “bruikleen lang”, but also whether something is medical equipment or not.

We also asked the respondents afterwards what would be the best ideas. Table 7 shows the answers. This turns out to be totally different ideas when comparing this to the top 5 ideas that follow from the impact effort analysis. First, this can be explained due to the effort these respondents would like to take to improve the Productdossiers. Second, both respondent 7 and the external reviewer mention the drop-down menu in point 3 above is not possible. Third, respondent 7 does not know the terms value-based procurement and best-value approach, and the external reviewer mentiones that this is not really related

to the Productdossier but more something in general for the purchasing department. Therefore, we do not consider the above mentioned point 3 and 4. The ideas that are mentioned at least twice are the following four: make required documents mandatory, think about disconnecting the Productdossier and the Aanschafdossier, clearly make a distinction for which products to make a Productdossier and for which not, improve the education for appliers and reduce the number of appliers.

Table 7 Top five improvement ideas per respondent

Respondent	Top five idea	Idea
1	1	Increase awareness of the functionality of this component. Make sure people do not see this as a way how to get the product or to receive a ref. number.
	2	Make the required documents during the process mandatory. This could save time for employees that are controlling the products at a later stage.
	3	Think about disconnecting the Productdossier and the Aanschafdossier.
	4	Make the product requirements document smaller and easier to fill in.
	5	Make conscious decisions for which products to start a Productdossier and what needs to be documented. For example, if it is medical equipment, a Productdossier needs to be made and then components A, B, C and D are necessary to fill.
7	1	Better educate the stakeholders
	2	Reduce the amount of appliers
	3	Make documentation mandatory
	4	Improve the process and make a distinction in when to make a Productdossier for which product
	5	Communication (related to the systeem)
External	1	Less appliers, so they know better how to fill it in. Educate these people better and get time to do that.
	2	Connection between projects and Productdossier
	3	Disconnect Productdossier and Aanschafdossier
	4	Start the evaluation plan
	5	Raise consciousness and awareness

When combining the results, we conclude the following regarding improvement ideas. According to the impact effort analysis, we would suggest to keep the content of component 1 short and simple, make sure applicants ask about the content of component 1 to the person wo wants to use the product and clearly define terms. According to the top five of the people who reviewed the list, we suggest to make required documents mandatory, think about disconnecting the Productdossier and the Aanschafdossier, clearly make a distinction for which products to make a Productdossier and for which not, improve the education for appliers and reduce the number of appliers.

5. Conclusion and discussion

In this chapter, we discuss the results of this research. In Section 5.1, we answer the research question and discuss the results. We link the results of our research to the theory on red tape and place the Productdossier and its components in the red tape scale. Section 5.2 describes the implications of this research and gives recommendations to stakeholders and recommendations for further research. Last, we will elaborate on the reliability and the validity of this research and the limitations and strengths of this research in Section 5.3.

5.1 Conclusion

In this research, we answer the following research question:

"In how far do stakeholders in hospitals perceive the Productdossier as functional and as burdensome, and how could this be improved?"

To conclude, stakeholders perceive the components of the Productdossier as part of the Aanschafdossier as functional in enhancing patient safety in the hospital, but at the meantime they experience a high compliance burden.

When looking at the separate components of the Productdossiers, we conclude the following. The first component, the need for the new product, is functional but not for patient safety enhancement and the compliance burden is low. The second component, the product requirements document of the healthcare facility, is not functional for the enhancement of patient safety. The compliance burden of the component is high. The third component, the risk analysis, is important for patient safety enhancement. Meanwhile, the compliance burden is expected to be high for the stakeholders involved. Within the fourth component, education is considered as functional to increase patient safety, however, documenting the education plan in the Productdossier is currently not experienced as improving patient safety. The compliance burden is varies. Respondents expect the fifth component, the periodic evaluation plan, not to be functional to increase patient safety and the compliance burden is expected to vary.

Based upon the improvements described in 4.5, we recommend the following. Content-related, hospitals should improve the following to contribute to a higher extent to patient safety. First, process designers should change the process to improve the quality of the Productdossiers, by making distinctions in the

risk and costs of products. This is based upon the fact that respondents often make distinctions in this. Second, product controllers (or other functions) should have a clear job description to control the quality of the Productdossiers to prevent unnecessary products in the hospital and thus unnecessary Productdossiers. Third, the process designers should evaluate the performance and the current management of applicants. Fourth, process designers should design a process for a periodic evaluation plan. Fifth, the hospitals have to search for collaborations with other hospitals. In the remainder of this chapter, we further elaborate on these recommendations. According to the top five of the people who reviewed the list, we suggest to make required documents mandatory, think about disconnecting the Productdossier and the Aanschafdossier, clearly make a distinction for which products to make a Productdossier and for which not, improve the education for appliers and reduce the number of appliers.

An interesting finding is that respondents make the distinction in the sort of product, whether costs are high or low and whether risks are high and low. Respondent 4 particularly did this when scoring the components on functionality and compliance, but also other respondents mention this. Therefore, the nature of the product can also be considered to be important when researching the perception of employees on the Productdossier. Therefore, we also think it is important to make a clear distinction for which products to make a Productdossier and for which it is unnecessary.

5.2 Recommendations and implications

This research has a few implications and holds a few recommendations to hospitals and for further research. As we concluded from this research that Productdossiers are perceived to be functional to patient safety, we implicate hospitals to continue making Productdossiers for new products. We found that the process regarding Aanschafdossiers is not experienced as red tape. In general, we recommend hospitals to find strategies to reduce the compliance burden to alter a shift in the red tape scale from necessary bureaucracy towards high quality rules. In this section, we explain how that is possible. Further research needs to be performed on how the burden could be reduced, but this study implies that the Productdossier causes much pressure at work, takes much time to comply with, causes many delays and creates a lot of frustration [1]. Hopefully, this exposure is an incentive for hospitals to reduce compliance burden. Reduction of compliance burden may improve the quality of Productdossiers. In general, we advise hospitals to collaborate and share relevant knowledge regarding the processes of the Aanschafdossier and the content of Aanschafdossiers or Productdossiers.

This research adds *scientific value* to the existing literature in several ways. First, this research extends on Schoten et al. [13] towards healthcare-related damage within deceased patients in Dutch hospitals. It adds to the main message that actions aimed at incident prevention reduce the number of incidents. In general, actions that enhance on patient safety and incident prevention like inspections, accreditation, protocols and guidelines, product measures and incident reporting are regularly described in literature. In this research, we used literature of the WHO [15], Rijksoverheid [19], Hussein et al. [20], Woolf et al.[21], Schoten et al.[13], IoM [2], Wagner [3] and Brown et al. [22] to support this. However, in none of these, nor in other literature, the effect of the Productdossier nor Aanschafdossiers in Dutch hospitals has been assessed. This is difficult research to do as following from the Swiss Cheese model [17]. Therefore, this research adds new knowledge to the existing literature on patient safety and incident prevention. Also, this research supports the usage of the Covenant, as this research concludes that the usage of a Productdossier is functional. Another scientific contribution that this research makes is the usage red tape of Van Loon et al. [1]. This theory has been used in healthcare research already, for example in the research of the health insurer IZZ [30]. However, this has not been used to evaluate patient safety actions. This research contributes to connecting a healthcare topic to a rather public administration theory. Also, this research is of scientific value as it recommends ideas for further research. These will be described at the end of this section.

Next to scientific contribution, this research also has *practical relevance*. This research generates ideas for process improvements for the organisation as described in Section 4.5. We already noticed that this research provoked a discussion at Isala and that it stimulates stakeholders to change the process with the aim to reduce the compliance burden. This research highlights a few bottlenecks that can be improved to design an efficient and streamlined processes in both Isala and Máxima MC. This positively influences the compliance burden for stakeholders and healthcare expenditures. Also, a better process regarding the Productdossier and thus the quality of Productdossier eventually lead to a higher level of patient safety. In the following paragraphs, we describe the recommendations for hospitals how to deal with the data after the publication of this study.

We recommend hospitals start the discussion with stakeholders about the improvements given in Section 4.5 to change the process. Process designers and managers have to take the lead. We especially think that redesigning and evaluating the process helps the stakeholders. The process should be simplified to increase the quality of the Productdossiers. We emphasise maintaining the quality of Productdossiers, as we now proved that it is enhancing patient safety, but to make conscious decisions

about what is required and which steps for particular process steps are irrelevant and cause a high compliance burden. In particular, we advise Isala to make a clear distinction in the origin of the products and determine early in the process which type of product the application concerns. This is in line with the process at Máxima MC. Máxima MC is currently already reconstructing its process for CBMH requests, therefore we would advise this hospital to continue while considering the PDCA cycle meanwhile. Together with this recommendation, we advise the hospitals to evaluate the number of stakeholders and applicants in this process. We recommend applicants consciously to think about whether they have the right knowledge and are the right person to apply for a new product.

Also, as we concluded that 7 of the 9 respondents think the evaluation is important for hospitals, we recommend hospitals to think about the construction of component 5: a periodic evaluation plan. Even though it might not seem to contribute to patient safety, evaluation entails a lot of advantages as described in Section 2.3. The framework of Brewster et al. [29] could be used as the basis for a periodic evaluation plan. This frameworks focuses on 'managing collaboration and uncomfortable realities', we think this could be valuable. Also, we recommend taking a look at the process of component 3 as a guideline for the development of the process of this component.

During the preliminary research as described in Appendix K, we noticed several topics that are relevant in the future concerning Productdossiers: availability of products (and alternatives of backorders), quality of medical equipment, safe use of products at home, sustainability, information safety and the evaluation of medical equipment. Regarding future development, these topics must be discussed within hospitals.

Even though these recommendations are helpful to improve the quality of Productdossiers, there are also some obstacles regarding the practical relevance. Hospitals are mandatory to comply with the Covenant. Stakeholders of the Productdossier are familiar with that, turns out from evaluation report of Aanschafdossier 2.0 [8]. Respondent 5 also claims "Actually, these are all rules forced by law to which we should comply with anyways, so I can say something about that, but that makes no difference." The safe use of medical technology by healthcare suppliers is mandatory and is part of the delivery of high-quality care [5]. When hospitals improve the current Productdossier using the ideas for improvements generated from this research, the stakeholders have to be conscious of the Covenant. We recommend that hospitals comply with the Covenant, nevertheless, consciously think about whether the information is needed and worth the pressure, time, delay and frustration. Another obstacle is the time it is expected to take to make adaptations to the process. That is caused by the organisation structure and the change

culture of the hospital [43]. Key factors that are identified that impede culture change in healthcare are inadequate or inappropriate leadership; constraints imposed by external stakeholders and professional allegiances; perceived lack of ownership; and subcultural diversity within health care organizations and systems. All of these four are also notified at least once in the interviews to negatively influence changes in Productdossier. Therefore, we advise that someone takes the lead, ownership should be created over the different steps in the process, perspectives of external stakeholders and professionals should also be included, and all stakeholders should be involved.

Patient safety remains a hot topic in healthcare and therefore we recommend further research on Aanschafdossiers and Productdossiers. First, we recommend performing a follow-up research on a larger scale in multiple hospitals in The Netherlands using quantitative research, wherein the literature review and the outcomes of this research serve as a ground. This could examine whether the conclusions of this research also hold for other hospitals and stakeholders. A lot of respondents made assumptions towards the compliance burden of stakeholders, but it is interesting to interview all stakeholders towards their own perception per step in the process. Due to time limitations, we decided to delineate the Productdossier as part of the Aanschafdossier, and focus on the content instead of also on the process. As all hospitals during preliminary research encounter difficulties regarding process making, this is expected to be interesting for further research. First, hospitals could bundle both quantitative and qualitative research and present it to IGJ, NVZ and NFU or other policymakers to request a golden standard or set of measures on the Covenant. Second, further research on the Productdossier is needed on how this strategy relates to the other actions established in healthcare to prevent safety incidents in hospitals. This is relevant, as multiple actions are important in prevention as described by the Swiss cheese model in Section 2.1. The extent of the contribution of Aanschafdossiers compared to other strategies as described in Section 2.2 remains unexamined but is important to reflect this strategy towards others. Third, further research should examine in which circumstances Productdossiers prevent safety incidents, using a bottom-up strategy. This research could then be translated to improve its quality and process. Fourth, follow-up research could be performed towards the improvements given in this research regarding processes, evaluation plans and collaborations with other hospitals to determine change over time.

5.3 Limitations and strengths regarding reliability and validity

This research entails a few limitations that affect the validity and reliability of this research and has a few strategies to increase validity and reliability. Respondents could be biased according to their own experiences, beliefs and knowledge. This section describes the measures we took and describes the effect on validity and reliability during the stages of this research and how this affects the quality of this research. Our research also has a few strengths, these are also discussed in this research.

The most remarkable limitation that influenced the reliability and validity are the limitations regarding the terms *functionality* and *compliance*. To be objective during the research, we changed the dimensions of the red tape 'compliance burden' and the 'lack of functionality' retrieved by Van Loon et. al [1] to compliance and functionality. We changed this, as the original dimensions probably imply that the Productdossier does not contribute to patient safety and is difficult to comply with. Also, Van Loon et al. [1] use these terms in English and so are the terms functionality and compliance. As the interviews were held in Dutch, the terms were translated to "*functionaliteit*" and "*naleven*" in Dutch. However, this could result in misinterpretations by respondents and rephrasing and translating these terms holds a few limitations. Even though we explained the definition of these terms before the start of the interview and during the interview again if needed to every respondent using the same strategy according to the interview guide as described in Section 3.2, we noticed that the terms were interpreted wrong during a few interviews. Respondents often had ambiguous perceptions of compliance and functionality of components. Functionality was also seen as functional for the organisation. In the term compliance burden, respondents sometimes mentioned that something was not complied with (referring to the current status of the component). Also, we noticed during the interviews we did not clearly check whether there is a compliance burden creating the content within the Productdossier or whether we would like to reflect upon the actions that follow or need to be implemented. That is mainly relevant for component 3, 4, and 5. The compliance burden to fill the content of these components is low, while performing a risk analysis, educating people and evaluating a product is more time and effort taking. components are easy to comply with, the compliance burden These limitations could have been prevented by clearly defining this at the beginning and making respondents aware during the interviews.

We aimed to enhance the validity of the research by discussing interview schemes with the supervisors at the University of Twente and Isala, as well as performing pilot interviews on independent researchers in the affiliated with the University of Twente [44]. Also, the translation of the English interview guide to Dutch has been checked by an independent researcher of the University of Twente.

The sampling holds a few limitations and strategies regarding enhancing reliability and validity. First, we included two hospitals in this research to enlarge the external validity. However, it is still questionable to what extent this could directly be translated to other hospitals, as all hospitals in The Netherlands have a different process. Second, we aimed to interview at least ten respondents. The list of invitees was composed with a point of contact of the hospitals and so we invited at the beginning 5 respondents per hospital using a predefined list in Appendix B. As a consequence, relevant perspectives could be missing. Also, we noticed that even though we constructed a list of roles and functions in, this did not correspond to the functions. The stakeholders of Isala and Máxima MC that were assigned to the specific role are not completely comparable. Out of the 10 invitees, 9 responses were received. One respondent is added to the original list of respondents. Respondent 10, a healthcare professional was added from Isala during the process, as that perspective was considered by the researchers and other respondents to be relevant. Respondent 11 validated the research and gave the same answers that were already given during the research This is considered to be a strength of this research, as these wide variance of respondents creates a wide view on the perception of stakeholders. During the last interview with respondent 11, we noticed that data saturation was reached which is a strength of this research. We excluded scores of respondent 3 was excluded from the analysis as mentioned in Section 3.1.

During the interviews, we continuously monitored the adherence of spoken answers to the scale. In the case of respondents 9 and 10, we noticed a discrepancy between spoken answers and quantitative answers on the scale, by which we reminded them of the scale and the definition of functionality and compliance. After discussing this, the respondent corrected the numbers so that they correspond to their spoken answers. Another tactic we used during the interviews was to check the answer of the respondent by summarising their answer. The use of semi-structured interviews contributes to the high validity which is a strength of this research. During the interviews, we tried to reduce interviewer bias by not asking suggestive questions.

During data analysis, all interviews have been held, transcribed and coded by the same researcher. The reliability of this study could be enlarged by coding with two researchers and comparing the outcomes. To compensate for this lack and to enlarge the reliability, the transcripts have been coded multiple times until code saturation was reached [39]. During the coding, phrases have been divided into positive, negative and neutral based on the sentiment analysis. Even though opinions are checked with help of the scale, the division is subjective. Therefore, we decided to value some phrases to multiple codes. The multi-interpretable and ambiguous answers also lead to problems during the analysis: the

researchers noticed multiple quadrants were given to the component. Therefore, multiple dots are placed in the cross-analysis in Table 3 per component per respondent. Consequently, it is difficult to draw trustworthy conclusions from this cross-analysis. Interestingly, during the interviews, respondents mentioned their ambiguous perception was a result of the differentiation of costs of products, risk of products and sometimes also category of products (whether something was medical equipment or facility products). Another limitation of the cross-analysis table is that we used colours to indicate the density. These colours are used to give an indication but the classification is not based upon a theory.

When looking at the results per function in Table 3 and in Table 4, this research method and research strategy entail a few limitations. Even though this number of respondents is enough for data saturation as mentioned in the previous paragraph, the sample size of hospitals and respondents is too small to draw reliable conclusions when solely using quantitative data. Also, as a result of respondents giving ambiguous answers, respondents assigned more quadrants to the components than other respondents. As a consequence, the total number of times quadrants are assigned per function differs. For example, the aggregated number a process designer assigns one of the quadrants to the component is 11, while the managers in total only assigned 6.5 times a quadrant to the component. Therefore, we cannot make reliable conclusions on the different types of functions.

Furthermore, this research holds both strengths and limitations as we delineated the research. First, has been done by choosing for a focus on Productdossiers as part of the larger Aanschafdossiers. Second, this research focuses mostly on content and not on the process. Third, we only did qualitative research with help of quantitative parts. However, quantitative methods could give other interesting insights. Fourth, in the term functionality, we only included functionality towards patient safety, while functionality entails more than patient safety. As mentioned in the introduction, quality regulation in healthcare is important to achieve better patient outcomes and patient satisfaction, and it can lead to significant financial advantages [15]. This sharp delineation leads to a specific research, which is a strength. Meanwhile, this generates new ideas for further research. This will be discussed in the next section.

To conclude this research, the Productdossier contributes to patient safety but is difficult to comply with. To alter a change from necessary bureaucracy to the quadrant high-quality rules in the red tape scale, the first step for hospitals is to return to the drawing board with all stakeholders. Several strategies have been used to enlarge the validity and reliability of this research. However, due to ambiguous and multi-interpretable answers that were not either functional or high or low compliance, one has to keep

the nature of this research in mind. Improvements in the Aanschafdossier regarding the processes, evaluation plans and collaborations reduce the compliance burden and improve patient safety in hospitals in The Netherlands. Further research is needed to enhance patient safety in healthcare.

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Appendix A: Components of the Productdossier

In Table 8, we described the components of the Productdossier. In the second column, a description can be found as given in the Covenant [5]. In the third column, we translated this to English. In the last column, we give the shortened description which we will use in figures and tables.

Table 8 Components of the Productdossier

Component	Dutch description	English description	Shortened description
1	De noodzaak van de verwerving	Need for the new product	Need
2	Het programma van eisen van de zorginstelling	Product requirements document of the healthcare facility	Requirements document
3	Een risicoanalyse	Risk analysis	Risk analysis
4	De bekwaamheidseisen met bijbehorende scholing van de toekomstige gebruikers en technici	Competency requirements and corresponding education of future users and technologists	Education plan
5	Periodiek evaluatieplan	Periodic evaluation plan	Evaluation plan

Appendix B: Roles of stakeholders of the Aanschafdossier

Table 9 Roles and tasks regarding the Aanschafdossier

	Role	Task
A	Manager	Manager that is responsible for the Aanschafdossier, assigned by the board of directors
B	Process designer	Controller and changer of the process of the Aanschafdossier
C	Product controller	Controller of the new products
D	Purchaser	Purchaser of a new product
E	Applicant	Requester of a new product

The Board of Directors of a hospital is responsible to comply with the Covenant. The *manager* is assigned by the Board of Directors to make sure the organisation complies to the Covenant. In this research, we are going to interview the manager that is responsible of the Aanschafdossier. At Isala, this is the Purchasing manager.

The second group of respondents are the *process designers*; the persons that have the job to design, control and change the process regarding the Productdossier.

The third category of people we would like to involve are the *product controllers*. They assess all requests for new products. They have to check whether the product is already used at the hospital and check whether the information is complete. The administrators make a list of things that are required in the Aanschafdossier for that specific product. Later in the process, they check whether every step is filled in correctly. Therefore, they are the controllers of the Aanschafdossier and are involved in all of the five requirements.

Purchasers purchase the products after administrators give permission to buy the product. They have to put relevant information into the workflow in Zenya. In between 2019 and 2021, 15 purchasers were involved in the process at Isala [8].

Applicants are responsible for the application of new products on their ward and use the products. Applicants are the representatives of the (medical) staff of their ward. They describe the need for the new product and specify why other products that are already in use are not sufficient. Next to that, they

describe the product requirements. They help with the risk analysis and write a plan for the education. Also, they help with the evaluation. Therefore, they are involved in all requirements. On several wards, there are multiple employees who can apply for new products. Also, there is a large difference between the frequency of application per person. In between 2019 and 2021, 241 employees at Isala did an application for a new product [8]. Preferably, we would like to include applicants that are working at the workplace as well.

Appendix C: Interview guide (English)

Introduction

Thank you for letting me interview you! I am Judith de Boer, and I am currently researching the contribution of the Aanschafdossier to patient safety. This research is conducted by the purchasing department at Isala. My research is complementary to a research conducted last year at Isala by a student of Rijksuniversiteit Groningen. This research was an evaluation that focused on the process of the Aanschafdossier. In this research, I will focus on the content of the Productdossier and I will consider the five different components of this Productdossier. This research aims to gain new insights into the relationship between the Productdossier and patient safety.

This interview will take a maximum of one hour. This interview is divided into three parts. First, I will ask some introduction questions and some general questions about the Aanschafdossier. After that, we will look into the 5 components of the Productdossier and will discuss the functionality and the compliance per component. At last, I have a few closing questions.

I would like to say once more that you could decide at any moment in time to stop this interview or drawback, even without giving the reason.

Do you give permission to record this interview to process the information for my research?

- Yes → Then we will start the interview now.
- No → Then we will stop the interview now.

At first, I want to make sure that the definitions of the Productdossier and the Aanschafdossier are clear. The Aanschafdossier is the bigger file and functions a framework for multiple processes. The Aanschafdossier focuses on the total purchasing of a specific new product. The Productdossier is a part of the Aanschafdossier. The Productdossier describes about the product itself, but not about the purchasing. The Productdossier as described in the "Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg". That are the following: need for the new product (1), product requirements document of the healthcare facility (2), risk analysis (3), competency requirements and corresponding education of future users and technologists (4) and a periodic evaluation plan (5).

Then I would like to start the interview now.

	Component	Topic	Question
	Introduction interview	General	- What is your function within the hospital? - In what way are you involved in the Productdossier? - Do you think the Aanschafdossier in general contributes to patient safety within the hospital? And if yes, how? And if no, why not?

After these general questions, we would like to focus on the five components of the Productdossier, as described in "Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg". That are the following: need for the new product (1), product requirements document of the healthcare facility (2), risk analysis (3), competency requirements and corresponding education of future users and technologists (4) and a periodic evaluation plan (5). Are you familiar with these components?

- Yes → Continue to the questions
- No → Explanation of the components (using the cards)

The first component, '*Need for the new product*' describes why the product is needed in the hospital and why it is different compared to the other existing products used or in the assortment [7]. The goal of this component is to clarify the objective of purchasing the new product is clear and to prevent multiple unnecessary similar products.

The second component in the Productdossier is a *product requirements document of the healthcare facility*. This entails the requirements, behaviour, functionality and features a new product has to meet according to the healthcare facility. Also technical and physical attributes are described, or logistical requirements in terms of volume and delivery times are specified [23].

The third component of the Productdossier is a *risk analysis*. The risk analysis is used to identify, recognize, and describe potential problems, to prevent safety issues[25]. Sometimes, risks are acceptable, and do benefits outweigh the drawbacks of the risk.

The fourth component in the Productdossier is describing the *competency requirements and corresponding education of future users and technologists* [7]. This includes an inventory whether new education or instructions are needed, by checking the current competency requirements and the wished

competency requirements. After that, a plan is constructed how to educate the future users and technologists about the new product.

The fifth and last component in the Productdossier is a *periodic evaluation plan* of the new product. This information entails a plan for the periodic evaluation after commissioning the new product of a certain period of time. During the evaluation, the following points are addressed: what goes right, what could be improved, does the product achieve the desired results, does it fulfil the wishes and what should be improved.

	Component	Topic	Question
1	Need for the new product	Current status	- To what extent do you think the content of the component *Need for the new product* is filled in in the right way at this moment?
		Functionality	The functionality of a component can be defined as whether it is useful in achieving a certain goal, namely patient safety. If the functionality of a certain component is low, it is not suitable to achieve patient safety. If the functionality of a certain component is high, it is suitable to achieve patient safety. - On scale of 1 to 5, how would you rate the component *Need for the new product* on base of functionality, so whether it contributes to achieving the goal of patient safety? 1 would be not functional (and that it does not contribute to patient safety) , 5 would be a very functional (and that it does contribute to patient safety). - Could you explain your answer?
		Compliance	The compliance of a component can be defined as the amount of excessive or unnecessary amount of work pressure, time, delay and/or frustration it costs for the employee to comply with this component, *Need for the new product*. If the compliance is low, you experience a low amount of work pressure, extra time, delay and/ or frustration. If the compliance is high, you experience a high amount of work pressure, extra time, delay and/ or frustration. - On scale of 1 to 5, how would you rate this component on base of compliance? 1 would be easy to comply with (and it costs not a lot of work pressure, time, delay and/or frustration), 5 would be very difficult to comply with (and it costs a lot of work pressure, time, delay and/or frustration) - Could you explain your answer?
		Improvements	- What could content-related be changed to the component *Need for the new product* to improve the increase the added value of this component to patient safety?
2	Product requirements document of the healthcare facility	Current status	(same as component 1, etc.)
		Functionality	
		Compliance	
		Improvements	
3	Risk analysis	Current status	(same as component 1, etc.)
		Functionality	
		Compliance	
		Improvements	
4	Competency requirements	Current status	(same as component 1, etc.)

	and corresponding education of future users and technologists		
		Functionality	
		Compliance	
		Improvements	
5	Periodic evaluation plan	Current status	(same as component 1, etc.)
		Functionality	
		Compliance	
		Improvements	
	Ending		- Are there statements you did or answers you gave during this interview that you would like to revise? - Do you have any further comments of questions about this topic you would like to share?

This is the end of the interview. Thank you for your contribution and your time!

Appendix D: Interview guide (Dutch)

Dankuwel dat ik u mag interviewen! Ik ben Judith de Boer en ik doe een onderzoek naar het Aanschafdossier vanuit de afdeling Inkoop van het Isala. Mijn onderzoek is een aanvulling op een evaluatie van het Aanschafdossier door een studente van de Rijksuniversiteit Groningen van afgelopen jaar. In haar onderzoek is destijds gefocust op het proces van het Aanschafdossier, in mijn onderzoek focus ik op de inhoud van het Productdossier. Het doel van dit onderzoek is om nieuwe inzichten te krijgen over het Productdossier en de relatie tot patiëntveiligheid.

Dit interview duurt maximaal één uur. Dit interview is verdeeld in drie onderdelen. Als eerste wil ik in de introductie wat inleidende en algemene vragen stellen. Daarna wil ik dieper ingaan op vijf onderdelen van het Productdossier, en daarbij kijken of het functioneel en/of belastend wordt ervaren. Als laatste heb ik nog een paar afrondende vragen.

Ik wil nogmaals benoemen dat u op elk moment mag besluiten om dit interview te onderbreken of om u terug te trekken, ook zonder dat u een reden hoeft te geven daarvoor.

Bent u er akkoord mee dat ik dit interview opneem voor uitwerkingsdoeleinden?

- Ja → Dan beginnen we nu met het interview.
- Nee → Dan eindigt het interview hier.

Als eerste wil ik zorgen dat de definities van het Productdossier en het Aanschafdossier duidelijk zijn. Het Aanschafdossier is als het ware het grote geheel en kan gezien worden als een kapstok waarbij processen zijn ingericht. Het Aanschafdossier richt zich op de gehele aanschaf van een bepaald nieuw product. Het Productdossier is een onderdeel van het Aanschafdossier. Het Productdossier zegt alleen wat over het product zelf, en niet over de aanschaf ervan. Het Productdossier zoals deze beschreven staat in het Convenant bestaat uit vijf onderdelen: de noodzaak van de verwerving (1), het programma van eisen van de zorginstelling (2), een risicoanalyse (3), de bekwaamheidseisen met bijbehorende scholing van de toekomstige gebruikers en technici (4) en een periodiek evaluatieplan (5).

Dan wil ik nu beginnen met het interview.

	Onderwerp	**Onderwerp**	**Vraag**
	-	Algemeen	- Wat is uw functie binnen het ziekenhuis?

			- Op welke manier heeft u te maken met het Productdossier? - Denk je dat het aanschafdossier in het algemeen bijdraagt aan de patientveiligheid binnen het ziekenhuis? En zo ja, hoe? En zo nee, waarom niet?

Hierna focussen we ons op de vijf componenten uit het Productdossier zoals ze beschreven staan in "Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg". Dat zijn de volgende: de noodzaak van de verwerving (1), het programma van eisen van de zorginstelling (2), een risicoanalyse (3), de bekwaamheidseisen met bijbehorende scholing van de toekomstige gebruikers en technici (4) en een periodiek evaluatieplan (5). Bent u bekend met deze onderdelen?

- Ja → ga verder naar de vragen
- Nee → Uitleg over de componenten (met behulp van kaartjes)

Het eerste component, *de noodzaak van de verwerving* omschrijft waarom het nodig is om het nieuwe product aan te schaffen voor het ziekenhuis en waarom verschilt met de producten die op dit moment gebruikt worden of in het assortiment zitten. Het doel van dit component is om te zorgen dat het doel van het aanschaffen van dit nieuwe product duidelijk is, en om er voor te zorgen dat er meerdere onnodige vergelijkbare producten in het assortiment zitten.

Het tweede component in het Productdossier is het *programma van eisen van de zorginstelling*. Dit beschrijft voorwaarden, gedrag, functionaliteit, eigenschappen waaraan een nieuw product moet voldoen volgens de zorginstelling. Ook kunnen technische en fysieke eigenschappen worden beschreven, net als logistieke voorwaarden zoals het aantal of levertijd.

Het derde component is een *risicoanalyse*. De risico analyse wordt gebruikt potentiële problemen te identificeren, herkennen en beschrijven, met als doel om veiligheidsincidenten te voorkomen. Sommige risico's zijn acceptabel en dan wegen de voordelen op tegen de nadelen van het risico

Het vierde component is de *bekwaamheidseisen met bijbehorende scholing van de toekomstige gebruikers en technici.* Dit houdt in om te bepalen of er nieuwe scholing of instructies nodig zijn, door te kijken naar de huidige capaciteiten en kennis en bekwaamheid van het personeel. Daarna kan een plan voor scholing of instructies worden gemaakt.

Het vijfde en laatste component in het Productdossier is een *periodiek evaluatie plan* voor het nieuwe product. Deze informatie houdt een plan in om een evaluatie te doen na een bepaalde periode van tijd na de ingebruikname. Tijdens de evaluatie kunnen de volgende punten worden geëvalueerd: wat gaat er goed, wat kan er verbeteren, behaalt het product de gewenste resultaten, voldoet het product aan de wensen en wat kan er verbeterd worden.

	Onderwerp	Onderwerp	Vraag
1	De noodzaak van de verwerving	Huidige status	- In hoeverre denkt u dat de inhoud van dit component, *De noodzaak van de verwerving* op deze manier op de juiste manier wordt ingevuld?
		Functionaliteit	Met de functionaliteit van een onderdeel wordt bedoeld of het geschikt is om een bepaald doel te behalen; namelijk patiëntveiligheid. Als de functionaliteit van een onderdeel laag is, dan is het niet geschikt op patiëntveiligheid te behalen. Als de functionaliteit van een component hoog is, dan draagt het bij aan het garanderen van patiëntveiligheid. - Op schaal van 1 tot 5, hoe zou je de functionaliteit beoordelen bij dit component, *De noodzaak van de verwerving*, draagt het bij aan het doel van patiëntveiligheid? Hierbij betekent **1** dat u vindt dat het niet functioneel is en dus niet bijdraagt aan patiëntveiligheid, en **5** dat u vindt dat het heel functioneel is en dus veel bijdraagt aan patiëntveiligheid. - Kan u uw antwoord uitleggen?
		Naleving	De naleving is de mate waarin een onderdeel wordt gezien als een last om het uit te voeren, door overmatig of onnodig veel tijd, energie of andere middelen er aan te besteden. Als er sprake is van weinig lasten om het component na te leven, kost het de werknemers weinig werkdruk, tijd, vertraging en/of frustratie. Als er sprake is van veel lasten om een component na te leven, kost het de werknemers veel werkdruk, tijd, vertraging en/ of frustratie. - Op schaal van 1 tot 5, hoe zou u de nalevingslast beoordelen bij dit component, *De noodzaak van de verwerving*? Hierbij betekent **1** dat u geen lasten ervaart om dit uit te voeren, en **5** dat u veel lasten ervaart om dit uit te voeren. - Kan u uw antwoord uitleggen?
		Verbeteringen	- Wat kan er inhoudelijk veranderd worden aan dit component, *De noodzaak van de verwerving*, met als doel om de toegevoegde waarde aan patiënt-veiligheid te vergroten?
2	Het programma van eisen van de zorginstelling	Huidige status	(hetzelfde als component 1, etc)
		Functionaliteit	
		Nalevingslast	
		Verbeteringen	
3	Risicoanalyse	Huidige status	(hetzelfde als component 1, etc)
		Functionaliteit	
		Nalevingslast	
		Verbeteringen	
4	De bekwaamheidseisen met bijbehorende	Huidige status	(hetzelfde als component 1, etc)

	scholing van de toekomstige gebruikers en technici		
		Functionaliteit	
		Nalevingslast	
		Verbeteringen	
5	Periodiek evaluatieplan	Huidige status	(hetzelfde als component 1, etc)
		Functionaliteit	
		Nalevingslast	
		Verbeteringen	
	Afronding		- Dan zijn we nu bij het einde van het interview aangekomen. Zijn er opmerkingen of antwoorden die u hebt gegeven tijdens dit interview waar u op terug wil komen? - Heeft u nog andere opmerkingen/ vragen over dit onderwerp die u graag wil delen?

Dit is het einde van het interview. Dankuwel voor uw bijdrage en uw tijd!

Appendix E: Informed consent letter

Informatieblad voor onderzoek “Het verwachte effect van Productdossiers op patiëntveiligheid in ziekenhuizen in Nederland”

Doel van het onderzoek

Het doel van dit onderzoek is om inzicht te krijgen in de perceptie van werknemers in het ziekenhuis over de bijdrage van het Aanschafdossier aan de patiënt veiligheid.
De gegevens zullen gebruikt worden om nieuwe inzichten te krijgen in de huidige inhoud van het Productdossier en hoe dit verbeterd kan worden. De onderzoeksgegevens worden gebruikt om een rapport op te stellen wat gedeeld kan worden met andere ziekenhuizen in Nederland. De gegevens zullen geanonimiseerd worden.

Hoe gaan we te werk?

U neemt deel aan een onderzoek waarbij we informatie zullen vergaren door middel van semi-gestructureerde interviews. Dat wil zeggen dat er vooraf een lijst met vragen is opgesteld op basis van literatuur, oriënterende interviews en ervaringen. Deze zullen tijdens het interview gesteld worden, en mogelijk zal hier op doorgevraagd worden om extra informatie te verkrijgen. Het interview duurt maximaal één uur.
De onderzoeker maakt met u een afspraak. Het is ook mogelijk om dit interview online te houden, dit zal dan gedaan worden via Microsoft Teams. Als u digitaal wilt meedoen aan het interview, dan mag u dat via e-mail bij de onderzoeker aangeven. De onderzoeker zal in dat geval via e-mail een uitnodigingslink sturen.

We zullen dit interview opnemen via een audio-opname. Hier wordt nogmaals toestemming voor gevraagd aan het begin van het interview. Met de opname wordt het interview letterlijk uitgetypt, zodat deze op een complete en gestructureerde manier uitgewerkt kan worden. De geluidsopnames worden vernietigd worden na afloop van het onderzoek. De transcripten zijn opvraagbaar bij de onderzoekers en worden na vijf jaar verwijderd van de schijf.

Inhoud van het onderzoek

Het onderzoek bestaat uit ongeveer 25 vragen, afhankelijk van uw functie en kennis over de bepaalde componenten. Allereerst worden er een aantal algemene vragen gesteld. Daarna is onderzoek wordt opgedeeld in 5 componenten, zoals ze ook beschreven staan in “Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg”: de noodzaak van de verwerving (1), het programma van eisen van de zorginstelling (2), een risicoanalyse (3), de bekwaamheidseisen met bijbehorende scholing van de toekomstige gebruikers en technici (4) en het periodiek evaluatieplan (5). Per component zullen we focussen op de volgende vier onderwerpen: huidige staat, functionaliteit, nalevingslast en verbeteringen. Daarna worden nog een aantal afrondende vragen gesteld en is er natuurlijk ook de mogelijkheid voor opmerkingen en vragen vanuit uw kant.

Een aantal voorbeelden van vragen die worden gesteld tijdens het interview zijn:

- In hoeverre denkt u dat de inhoud van het component ‘risico analyse’ op de huidige manier op de juiste manier wordt ingevuld bij uw organisatie?
- In hoeverre denkt u dat het component ‘scholingsplan’ functioneel is, en bijdraagt aan het doel om hogere patiëntveiligheid te kunnen bieden?
- Wat zou er inhoudelijk verbeterd kunnen worden aan het component ‘evaluatieplan’, met als doel om de patiëntveiligheid te verbeteren?

Uitsluitend ten behoeve van het onderzoek zullen de verzamelde onderzoeksgegevens worden gedeeld met andere ziekenhuizen in Nederland. Dit heeft als doel om relevante conclusies en aanbevelingen te delen met andere ziekenhuizen, om zo bevindingen te delen, de uitvoering van het Aanschafdossier te verbeteren en mogelijk de bijdrage van het Aanschafdossier aan patiënt veiligheid te verbeteren.

Potentiële risico's en ongemakken

Er zijn geen fysieke, juridische of economische risico's verbonden aan uw deelname aan deze studie. U hoeft geen vragen te beantwoorden die u niet wilt beantwoorden. Uw deelname is vrijwillig en u kunt uw deelname op elk gewenst moment stoppen. Het nadeel aan dit interview is dat het tijd kost.

Potentiële voordelen

Op dit moment heeft u geen (direct) voordeel van meedoen aan dit onderzoek. Wel kan er door uw deelname aan dit onderzoek nieuwe inzichten worden verkregen over het Aanschafdossier. Uw kennis en ervaring kan bijdragen aan de manier waarop dit wordt ingevuld en waarop het Aanschafdossier

invloed heeft op patiëntveiligheid. Dit onderzoek draagt bij aan wetenschappelijke kennis die uw organisatie kan gebruiken om te verbeteren. Ook biedt het u de kans om uw stem te laten horen.

Vergoeding

U ontvangt voor deelname aan dit onderzoek geen vergoeding.

Vertrouwelijkheid van gegevens

Wij doen er alles aan uw privacy zo goed mogelijk te beschermen. Er wordt op geen enkele wijze vertrouwelijke informatie of persoonsgegevens van of over u naar buiten gebracht. Voordat onze onderzoeksgegevens naar buiten gebracht worden, worden uw gegevens zoveel mogelijk geanonimiseerd. In een publicatie zullen anonieme gegevens of pseudoniemen worden gebruikt. De audio-opnamen, formulieren en andere documenten die in het kader van deze studie worden gemaakt of verzameld, worden opgeslagen op een beveiligde locatie bij het Isala en op de beveiligde (versleutelde) gegevensdragers van de onderzoekers. De onderzoeksgegevens worden bewaard voor een periode van 10 jaar. Uiterlijk na het verstrijken van deze termijn zullen de gegevens worden verwijderd. Onderzoeksgegevens worden indien nodig (bijvoorbeeld voor een controle op wetenschappelijke integriteit) en alleen in anonieme vorm ter beschikking gesteld aan personen buiten de onderzoeksgroep.

Tot slot is dit onderzoek beoordeeld en goedgekeurd door de ethische commissie van de faculteit BMS de Universiteit Twente.

Vrijwilligheid

Deelname aan dit onderzoek is geheel vrijwillig. U kunt als deelnemer uw medewerking aan het onderzoek te allen tijde stoppen of pauzeren, of weigeren dat uw gegevens voor het onderzoek mogen worden gebruikt, zonder opgaaf van redenen. Het stopzetten van deelname heeft geen nadelige gevolgen voor u.

Dit onderzoek wordt geleid door Judith de Boer. Indien u vragen heeft over het onderzoek kan u contact opnemen met haar. De onderzoeksleider is studente Health Sciences aan de Universiteit Twente. Zij voert dit onderzoek uit in opdracht van het Isala en ter afronding van haar master Health Sciences.

Email: J.n.de.boer@isala.nl (of judithndeboer@gmail.com vanaf april 2022 na het afronden van de opdracht)

Voor bezwaren met betrekking tot de opzet en of uitvoering van het onderzoek kunt u zich ook wenden tot de Secretaris van de Ethische Commissie / domein Humanities & Social Sciences van de faculteit Behavioural, Management and Social Sciences op de Universiteit Twente via ethicscommittee-hss@utwente.nl. Dit onderzoek wordt uitgevoerd vanuit de Universiteit Twente, faculteit Behavioural, Management and Social Sciences. Indien u specifieke vragen hebt over de omgang met persoonsgegevens kun u deze ook richten aan de Functionaris Gegevensbescherming van de UT door een mail te sturen naar dpo@utwente.nl.

Tot slot heeft u het recht een verzoek tot inzage, wijziging, verwijdering of aanpassing van uw gegevens te doen bij de Onderzoeksleider.

Hieronder staat het toestemmingsformulier. Dit kan tijdens het interview (mondeling) ingevuld worden.

Toestemmingsformulier

Door dit toestemmingsformulier te ondertekenen erken ik het volgende:

1. Ik ben voldoende geïnformeerd over het onderzoek door middel van een separaat informatieblad. Ik heb het informatieblad gelezen en heb daarna de mogelijkheid gehad vragen te kunnen stellen. Deze vragen zijn voldoende beantwoord.
2. Ik neem vrijwillig deel aan dit onderzoek. Er is geen expliciete of impliciete dwang voor mij om aan dit onderzoek deel te nemen. Het is mij duidelijk dat ik deelname aan het onder- zoek op elk moment, zonder opgaaf van reden, kan beëindigen. Ik hoef een vraag niet te beantwoorden als ik dat niet wil.

Naast het bovenstaande is het hieronder mogelijk voor verschillende onderdelen van het onderzoek specifiek toestemming te geven. U kunt er per onderdeel voor kiezen wel of geen toestemming te geven. Indien u voor alles toestemming wil geven, is dat mogelijk via de aanvinkbox onderaan de stellingen.

	JA	NEE
3. Ik geef toestemming om de gegevens die gedurende het onderzoek bij mij worden verzameld te verwerken zoals is opgenomen in het bijgevoegde informatieblad.	□	□
4. Ik geef toestemming om tijdens het interview opnames (geluid / beeld) te maken en mijn antwoorden uit te werken in een transcript.	□	□
5. Ik geef toestemming om mijn antwoorden anoniem te gebruiken voor quotes in de onderzoekspublicaties.	□	□
6. Ik geef toestemming om de bij mij verzamelde onderzoeksdata te bewaren en te gebruiken voor toekomstig onderzoek en voor onderwijsdoeleinden.	□	□
Ik geef toestemming voor alles dat hierboven beschreven staat.	□	

Naam Deelnemer: Naam Onderzoeker:

Handtekening: Handtekening:

Datum: Datum:

Appendix F: Coding

In Figure 7, an example of the part of codes used are shown. The full table is visible in an Excel document that can be retrieved via one of the researchers. In total, the codebook consists of 250 codes. The codes added during inductive coding are indicated with a bullet point in the codebook. The list of codes is connected to groups and folders, to structure the codes logically. The groups of the codes can also be found in this Excel document. An example of this can be found in Figure 8.

Code	Grounded	Code Groups	Added later
○ Checken	109		
• Checken score	10	MMC Isala	*
• Score algemeen	99	MMC Isala	*
○ Component 1	198		
• 1C General Isala	2	Component 1 Compliance component 1 Isala	
• 1C General MMC	0	MMC Component 1 Compliance component 1	
• 1C Negative Isala	14	Component 1 Compliance component 1 Isala	
• 1C Negative MMC	8	MMC Component 1 Compliance component 1	
• 1C Neutral Isala	2	Component 1 Compliance component 1 Isala	

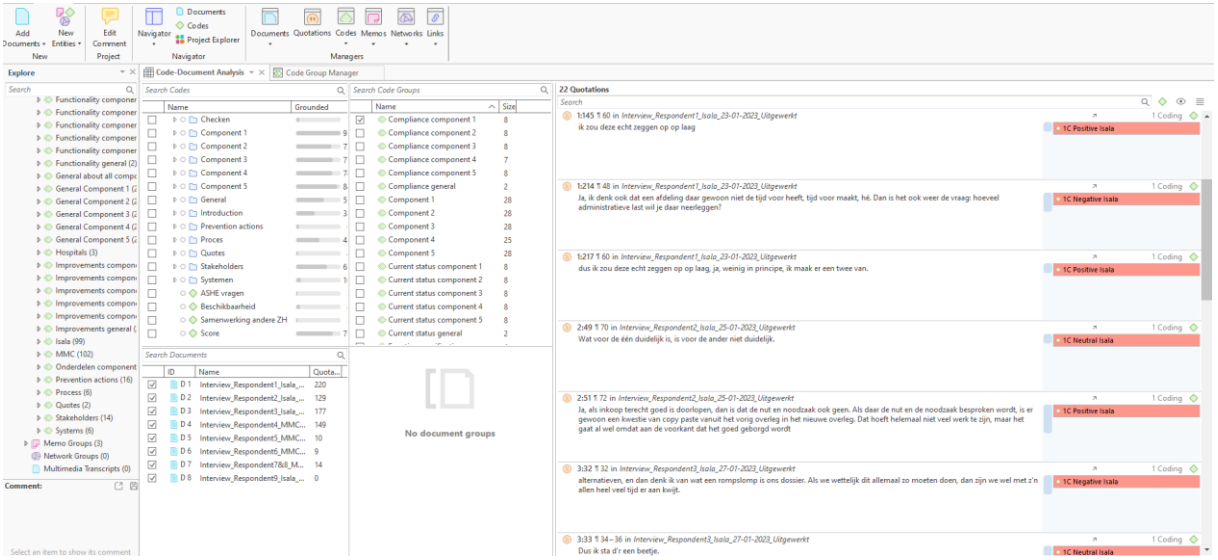
Figure 7 Example part of codes used

Groups	Codes	Code
Functionality general	2	Functionality general Isala Functionality general MMC
General Component 1	2	General Component 1 Isala General Component 1 MMC
General Component 3	2	General Component 3 Isala General Component 3 MMC
Process	8	Number of dossiers Isala Number of dossiers MMC Number of products Isala Number of products MMC Process Isala Process MMC Process creation Isala Process creation MMC
Improvements component 4	2	Improvement component 4 Isala ent 4 MMC

Figure 8 Example part of code groups used

Appendix G: Analysis in ATLAS.ti

In Figure 9, you can find an example of the Code-Document Analysis in ATLAS.ti. The projectbundle in ATLAS.ti is available on request via the researchers.



Appendix H: Results of the scale on functionality and compliance

Table 10 below shows the results respondents gave on functionality and compliance. The table has three remarks. First, in case the respondent could not decide between two answers, the average has been used in the average calculation. For example, respondent 7 filled in '2 or 3' in the scale for functionality for component 1, this has been written down in the table as 1,5 and this number is used for calculating the average. Second, in some situations, respondents did not want to assign a number to the components as it was not applicable or they did not felt the right person to judge upon this. Therefore, we noted n/a in the table. Third, respondent 4 divided the answers for component 2 and 3 into respectively investments and CBMH products. For example, the functionality of component 2 is scored as a 5 for investments and a 2 for CBMH products, therefore "5|2" is written down in the table. This division is also visible in the calculated averages. Last, respondent 3 did not assign any numbers in the scales, as all the knowledge on the Productdossier and Aanschafdossier they have is taught by respondent 4. Therefore, they said they did not have an unbiased idea and only gave other input during the interviews that would be relevant. They did never say that they were disagreeing the numbers respondent 4 gave.

		Respondents										
		A: Managers	B: Process designers		C: Product controllers				D: Purchasers	E: Applicant		Average
Component		1	2	3	4	5	6	7	8	9	10	
Functionality	1: Need	4	5	n/a	4	4	4	1.5	5	5	2.5	**4.4**
	2: Requirements document	5	4	n/a	5 | 2	4	5	5	2.5	n/a	4	**4.3 | 3.9**
	3: Risk analysis	5	5	n/a	5 | 3	4	5	5	4	5	4	**4.7 | 4.4**
	4: Education plan	5	5	n/a	3	4	5	4	4	5	4	**4.3**
	5: Evaluation plan	3	5	n/a	2	1	5	5	2	2	2	**3**
	Average	**4.4**	**4.8**	**n/a**	**3.8 | 2.8**	**3.4**	**4.8**	**4.8**	**3.8**	**4.3**	**3.5**	
Compliance	1: Need	2	2	n/a	3	4	4	1	2	4	3.5	**2.8**
	2: Requirements document	4	5	n/a	3.5 | 4.5	2	4	1	4	n/a	4	**3.4 | 3.6**
	3: Risk analysis	4	4	n/a	5 | 4	n/a	2	1	3	3	4	**3.3 | 3.1**
	4: Education plan	4	3	n/a	3	2	2	1	3	4	3	**2.8 | 2.4**
	5: Evaluation plan	n/a	4	n/a	4.5	3	3	1	4	1	4	**2.9**
	Average	**3.5**	**3.6**	**n/a**	**3.8 | 3.8**	**2.8**	**3**	**1**	**3.2**	**3**	**3.8**	

Table 10 Results scale on functionality and compliance

Appendix I: Quotes

In Table 11, we describe the original Dutch phrase that was later translated to English. In the last column, we noted the number of the respondent who said this.

Table 11 Translation of original quotes

Quote number	Quote in report	Original quote	Respondent number
1	I think it really contributes to the safe usage of medical equipment a lot.	Ik denk dat het echt heel veel bijdraagt wel aan het veilig toepassen van een medisch hulpmiddel.	5
2	We created a monster	Het is een draak van een systeem.	8
3	Our file is long-winded	Wat een rompslomp is ons dossier.	5
4	So sometimes, you feel like, is this deemed to be necessary?	Dus soms zit je ook wel eens van oke, is het allemaal nodig?	10
5	I appreciate laws and rules. This is what the rules prescribe, and I know what we need to do. But sometimes it is so much, sometimes it overshoots the mark. And then, it raises frustration, and people start to use the back door.	Ik hou wat dat betreft van wetgeving of van regeltjes. Ik weet, dit is wat er staat en dit moeten we doen. Maar het is zoveel soms, dat dat soms denk ik z'n doel voorbijschiet. En dan gaat het frustreren, dan gaan we dingen opkroppen en dan willen mensen het niet meer via de weg doen, met als gevolg dat mensen via de achterdeur dingen gaan doen.	4
6	When you look at the easiness, we have created a paper tiger. That creates an impressive administrative burden for hospitals	Als je kijkt, hoe makkelijk het is, dan hebben wij best wel een behoorlijke papieren tijger opgetuigd. Wat een best wel behoorlijke administratieve last neerlegt bij ziekenhuizen	1
7	It forces people to wrap their brain about the product they want. In case that is not clear, that will come to attention. (…) Will it become unsafer when you do not document this? Probably not.	je dwingt mensen, denk ik, er om, om wat in het koppie zit, zeg maar, op papier te zetten. En en dus als het niet een koppie zit, kom je er dan achter. (…) Wordt het onveiliger als je dat niet vastlegt? Vast ook niet.	4

8	a proliferation of new products within this hospital	om een wildgroei aan nieuwe producten binnen dit ziekenhuis te voorkomen	1
9	It is burdensome for people, we notice that, as it not performed well.	Het kost de mensen moeite, dat zien we, want het wordt niet goed gedaan.	8
10	I think it is a good call to have a few requirements, however, it would be better to consider the goal. I am looking for something for research, or something, or it could be smaller. A very comprehensive product requirements document does not increase quality for the patient. So, it can be smaller, easier, and it is not always necessary.	Denk dat het wel goed is om om een paar Eisen te hebben, maar meer dat je zegt, het doel is, ik zoek iets voor dit onderzoek of dat het veel kleiner kan. Een een heel uitgebreid pakket van Eisen maakt het voor de patiënt niet altijd beter. Dus het kan kleiner, makkelijker en niet altijd nodig.	8
11	false security	Schijnzekerheid	1
12	That takes up a lot of time.	Daar gaat heel veel tijd in zitten.	8
13	rest risk	rest risico’s	1
14	very functional	zeer *functioneel*	9
15	useful component	nuttig onderdeel	9
16	it contributes a lot to the quality of care.	in de kwaliteit van zorg draagt het heel veel bij.	7
17	regarding patient safety, it can harm patients	dan kun je patiënten risico, dan kan je de patiënten berokkenen	1
18	Absolutely. At the moment you introduce new products, you have to know what the possible risks are at the introduction of this product and which measures you have to take to reduce these risks.	Ja absoluut. Op het moment dat je nieuwe producten in gaat zetten, moet je goed weten wat mogelijk risico zijn bij de inzet van dit product en welke maatregelen je moet gaan nemen om die risico's te verkleinen	1
19	I think that it takes quite a lot of time	Ik denk dat dat best veel tijd kost.	2

20	The most work of the PRI is that you have to gather up with all stakeholders	Het meeste werk in de PRI zit hem in het feit dat je de mensen bij mekaar moet krijgen	7
21	everyone wants to have a finger in the pie	iedereen moet dan zo'n plasje er overheen doen	7
22	It is a lot to ask of an employee.	veel gevraagd is van een medewerker	8
23	it forces employees, applicants and wards to be conscious about education	dwingt wel om medewerkers om, om aanvragers, afdelingen, bewust te maken van dat er wat met scholing gebeurt.	7
24	very functional, very important. Yes, yes, it is really important that people are educated well.	heel functioneel, heel belangrijk. Ja, ja, het is gewoon heel belangrijk dat mensen goed geschoold zijn.	9
25	but all the applications that are done, it never pans out.	maar al die aanvragen die geweest zijn, daar wordt eigenlijk niks mee gedaan.	7
26	It is business as usual, it should be a piece of cake for them, but that costs time and effort.	Het is business as usual, het zou gewoon appeltje eitje moeten zijn voor ze, maar dat kost wel even tijd en werk.	7
27	Does it contribute to functionality of patient safety? Individually, I think not.	Draagt het bij aan de functionaliteit van patiëntveiligheid? Individueel, denk ik niet.	4
28	for the patient to a lower extent, but I think it is fundamental for an employee.	voor de patiënt wat minder, maar denk dat het dan meer voor de medewerker.	8
29	if you ruminate about which functions you need to group together, and one person of each function, then you can finish up the evaluation within half an hour till one hour.	als jij van tevoren goed nagedacht hebt, van welke mensen zouden we bij mekaar hebben en dan zal zal één iemand, dan kun je in een gesprek van een half uur tot een uur heb je. Heb je gewoon je evaluatie klaar.	7

30	The complexity can be found in the actions that need to be taken that follow from the evaluation plan.	Waar de complexiteit weer uitkomt is van de dingen die uit het evaluatieplan uitkomen.	7
31	product differs on content	product inhoudelijk verschillend	4
32	Actually, these are all rules forced by law to which we should comply with anyways, so I can say something about that, but that makes no difference.	Eigenlijk zijn dit allemaal wettelijke dingen waar we gewoon sowieso aan moeten voldoen, dus ik kan er wel wat van vinden, maar dat maakt niks uit.	5

Appendix J: Impact effort analysis

Component	Idea number	**Average impact**	**Average effort**	**Impact (0-5) (Respondent 1)**	**Effort (0-5) (Respondent 1)**	**Impact (0-5) (Respondent 7)**	**Effort (0-5) (Respondent 7)**	**Impa (0-5) (Exte**
Component 1: Need	1	3.3	1.0	4	1	4	2	2
	2	4.3	3.3	4	4	5	5	4
	3	3.7	2.3	1	1	5	2	5
	4	4.0	2.3	4	1	5	3	3
	5	3.3	4.3	5	4	5	4	0
	6	4.3	4.7	3	5	5	4	5
Component 2: Requirements document	7	3.0	3.0	4	2	5	5	0
	8	3.3	3.7	4	1	3	5	3
	9	2.3	4.7	4	5	0	5	3
	10	3.7	3.3	3	2	4	5	4
	11	1.0	2.0	3	1	0	0	0
	12	2.3	3.3	3	2	4	4	0
	13	1.0	4.7	1	5	0	4	2
Component 3: Risk analysis	14	2.7	2.3	3	1	0	3	5
	15	2.3	2.3	3	1	0	3	4
	16	1.7	3.3	2	2	0	3	3
	17	2.7	2.7	4	2	0	3	4
Component 4 Education plan	18	3.7	4.3	4	5	3	3	4
	19	4.0	3.0	4	4	3	3	5
	20	4.0	2.3	4	2	3	3	5
	21	2.7	3.7	5	4	3	3	0
Component 5: Evaluation plan	22	4.3	3.7	4	4	5	5	4
	23	3.7	4.0	4	2	5	5	2
	24	4.0	4.0	3	3	5	5	4
	25	3.3	3.3	4	1	5	5	1
	26	3.0	4.7	4	4	5	5	0
	27	4.7	2.3	4	1	5	5	5
	28	3.3	3.7	4	3	2	4	4
General	29	5.0	2.7	5	4	5	2	5
	30	5.0	3.3	5	4	5	2	5
	31	4.7	3.7	5	5	5	2	4
	32	3.7	3.7	5	3	2	4	4
	33	3.7	4.0	3	3	4	5	4
	34	3.7	3.0	1	1	5	5	5
	35	4.0	3.7	4	4	5	5	3
	36	3.3	4.3	5	5	2	5	3
	37	4.0	5.0	5	5	5	5	2
	38	4.7	3.3	5	5	5	2	4

	39	5.0	3.0	5	3	5	4	5
	40	4.0	3.7	5	4	5	4	2
	41	4.7	2.7	5	2	5	5	4
	42	4.0	2.0	4	1	5	2	3
	43	4.0	5.0	5	5	5	5	2

Appendix K: Conclusions of preliminary research about Aanschafdossiers and Productdossiers at eight hospitals

To obtain more insight into the current Aanschafdossiers and Productdossiers used at hospitals in the Netherlands, we had conversations with eight other hospitals in The Netherlands: Amsterdam Universitair Medisch Centrum, Deventer Ziekenhuis, Isala, Máxima Medisch Centrum, Medisch Spectrum Twente, Rijnstate, Ziekenhuisgroep Twente, and Ziekenhuis Gelderse Vallei. Amsterdam Universitair Medisch Centrum is an academic hospital, Ziekenhuis Gelderse Vallei is a generic hospital and the remaining five are top-clinical hospitals, like Isala. A pre-defined list of questions was used based on the Covenant, literature, and the evaluation at Isala, to have guidance during the conversations. This orientating research is used as background for the research, as there is little literature available on the current status of Aanschafdossiers and Productdossiers in hospitals. The conclusions can be found in this appendix.

This background research concludes in general that these hospitals all have a different process for their Aanschafdossier. As for all hospitals the starting point of their dossier was the Covenant, all content is comparable. However, there is no best practice described, neither gives the IGJ clear tools or guidance on how to design the process most effectively.

Summary of the conclusions

A sharp *vision* is crucial for the design of the process. The visions of the hospitals deviate a lot. The largest difference can be found in the categorization which will be explained in the next chapter. Most hospitals are continuously monitoring and controlling the workflow and the system. Every hospital mentions it will fit most of the regulations of the Covenant. However, in most systems, an evaluation is missing, or is only explicitly performed in case a product is used as test product or in case people think this is relevant.

As a result of *categorization* in Aanschafdossiers, the number of files varies a lot over the different hospitals: from 100 to 800 a year. Compared to Isala, this is relatively low. This could be explained by the fact that other hospitals do not make an Aanschafdossier for every product, as for example products are categorized and non-medical products or low-risk products follow a different procedure, which is not stored in the Aanschafdossier.

All hospitals distinguish products based on a category. The categories are defined as medical (supporting) equipment, medical software / ICT, implants, medical materials, medical disposables, re-sterilizable devices, in vitro diagnostics, laboratory devices, and others (non-medical). In some hospitals, these categories follow a different, less extended flow. Also, hospitals define based upon the risk that a product has how extended the file is. This happens beforehand. At Isala, there is also differentiation and less information collected.

Most examined hospitals refuse to compose a file for replacing products for *backorders*. Also, some hospitals only add information to the existing file, in case a new size, type, or brand of the product will be delivered. They mention the risk to safety and the effect is similar compared to the previously ordered product. Isala already does this for different sizes but does not apply this concept in case a different brand will be delivered or when it replaces a backorder.

Five hospitals use Zenya as a *system*. This is the same system used at Isala. Another hospital uses Excel, and the remaining hospital stores the documents on the local hard drive. When talking to Isala employees, there is a lot of resistance against Zenya, but this orientating study shows there is no other effective system that should be switched to.

In every hospital, a lot of *employees are in a way engaged* with the Aanschafdossier. Tasks are performed by a lot of different people in each hospital. When comparing hospitals to each other, people with similar functions perform different roles and have different duties and responsibilities in the process. The most noticeable difference, the executive department in Isala of the Aanschafdossier is the purchasing department, in other hospitals this is the Medical Technology department. Next to that, frequently advisory or controlling committees are used, like the Materiaal Advies Commissie (MAC), Medische Hulpmiddelen Commissie (MHC) and Commissie Beoordeling Medische Hulpmiddelen (CBMH).

Conclusions per subject

Op basis van de interviews zijn de volgende conclusies getrokken. Bij deze conclusies moet wel in acht genomen worden dat de punten niet zijn gevalideerd bij de respondenten en dat dit slechts als achtergrondinformatie gebruikt wordt. De conclusie is ingedeeld in de volgende onderwerpen: Visie op

het aanschafdossier, Categorieën, Medisch Convenant en inhoud, Stakeholders, Systemen, Optimalisatie en Toekomstbeeld.

Visie op het aanschafdossier

1. Het opstellen van een duidelijke visie over de inrichting van het Aanschafdossier is erg belangrijk. Een aantal ziekenhuizen heeft een duidelijke visie, anderen zijn hier nog mee bezig.
2. Het achterliggende doel van het Aanschafdossier is dat er risico's in kaart gebracht moeten worden omtrent veiligheid van de patiënt en werknemer, om zo incidenten te voorkomen. Een aantal ziekenhuizen noemen dat het invullen van het aanschafdossier ingevuld moet worden met dit doel in het achterhoofd houdend. Er moet niet doorgeslagen worden in regel- en administratiedruk.

Categorieën

3. De aantallen Aanschafdossiers die jaarlijks opgesteld worden zijn per ziekenhuis heel verschillend, dit varieert van 100 tot 800 per jaar. Deze aantallen zijn wel lager dan in het Isala, waar jaarlijks 1200 Aanschafdossiers worden gemaakt. Dit kan veroorzaakt worden door een duidelijkere splitsing waarvoor wél, en waarvoor geen aanschafdossier wordt gemaakt. Een kanttekening: het is moeilijk om hier gegronde conclusies op te baseren, aangezien er geen duidelijk overzicht is hoeveel nieuwe producten er in totaal over alle categorieën producten jaarlijks worden ingekocht. Ook heeft de grootte van een ziekenhuis hier invloed op.
4. Eén ziekenhuis heeft heel weinig producten in het Aanschafdossier. Zij hebben een concrete visie en maken een bewuste keuze maken op basis van risico welke producten wel in het aanschafdossier terecht komen en welke niet.
5. De meeste ziekenhuizen maken geen compleet aanschafdossier aan voor niet-medische hulpmiddelen, denk bijvoorbeeld aan spullen voor logistiek.
6. Bij elk ziekenhuis verlopen de categorieën producten andere flows. De categorieën zijn in veel ziekenhuizen verschillend. De volgende categorieën zijn genoemd: medisch (ondersteunend) apparatuur, Medische software/ICT, implantaten, medische materialen, medisch verbruiksmiddelen, (her-)steriliseerbare hulpmiddelen, in vitro diagnostica, laboratorium en overig (niet-medisch).

7. Een aantal ziekenhuizen maken geen aanschafdossier (meer) indien het product een vervangend product is. (backorders) Andere ziekenhuizen doen dit wel.
8. Een aantal ziekenhuizen breiden het oude dossiers van een product uit indien er een nieuw soortgelijk product wordt besteld, of indien er een toevoeging/ verandering aan het huidige product wordt besteld, in de vorm van een addendum.
9. Bij een aantal ziekenhuizen wordt ook een onderscheid gemaakt in investeringsaanvragen en financiering van producten. Vanuit dit onderscheid wordt een ander proces opgestart.

Medisch Covenant en inhoud

10. Elk ziekenhuis denkt enigszins te voldoen aan het Covenant. Veel ziekenhuizen hebben de evaluatie van producten niet geïncludeerd in het systeem. Zij evalueren alleen als dit vooraf besloten wordt dat dit moet, of als het gaat om een proefplaatsing. Veel respondenten geven aan dat dit te veel tijd zou kosten ten opzichte van wat het oplevert.
11. Qua inhoud komen de dossiers van de verschillende ziekenhuizen overeen; elk ziekenhuis heeft het proces ingericht aan de hand van het Covenant. Wel verschilt de inhoud per categorie, zoals wordt beschreven in bovenstaande punten. Dit onderzoek heeft geen inhoudelijke toetsing van dossiers gedaan.
12. Ziekenhuizen willen er uiteindelijk aan werken dat het aanschafdossier in de praktijk ook wordt toegepast; er moet bewustzijn gecreëerd worden op de werkvloer voor de risico's die uit een Aanschafdossier naar voren komen. Een aantal respondenten geven aan dat deze koppeling naar de praktijk nog mist.

Stakeholders

13. Bij alle ziekenhuizen zijn veel stakeholders betrokken bij het aanschafdossier. Als er iets veranderd wordt in het systeem, dan heeft dat gelijk veel betrekking op werknemers binnen het ziekenhuis.
14. Veel ziekenhuizen werken met een commissie die aanvragen beoordeeld of fungeert als adviesorgaan. Zo zijn er de Materiaal Advies Commissie (MAC), Medische Hulpmiddelen Commissie (MHC), Commissie Beoordeling Medische Hulpmiddelen (CBMH). Deze commissies hebben per ziekenhuis wel een andere samenstelling van deskundigen en een andere rol in het proces.

15. Bij een aantal ziekenhuizen wordt vooraf bepaald wat er nodig is voor het aanschafdossier van een product. Dat wordt gedaan a.d.h.v. inschatting van het risico van het product.
16. De verantwoordelijkheid van de uitvoering van het Convenant is bij veel ziekenhuizen verspreid over verschillende functies. Bij een aantal ziekenhuizen ligt veel verantwoordelijkheid bij de afdeling, zoals bij het Isala, bij een aantal andere ziekenhuizen ligt dit meer bij Medische Technologie.
17. In de meeste ziekenhuizen kunnen veel medewerkers een nieuwe aanvraag voor een product indienen. Dit wordt meestal wel eerst gecontroleerd door hun leidinggevende/ manager. In de praktijk wordt vaak gezien dat dit vaak door dezelfde mensen wordt gedaan.
18. Een aantal ziekenhuizen stelt een verantwoordelijke aan voor de aanvraag van het product. Deze verantwoordelijke zorgt er voor dat alle betrokkenen hun taken uitvoeren en dat het aanschafdossier compleet is. Bij sommige ziekenhuizen is dat de aanvrager, bij anderen is dat bijvoorbeeld een DSMH'er of een Medisch Technoloog of assortimentscoördinator.
19. Namen van functies en hun bijbehorende taken verschillen erg binnen ziekenhuizen.

Systemen

20. De meeste ziekenhuizen, 6 van de 8, gebruiken Zenya voor hun workflow. Het aanschafdossier van één ziekenhuis staat in mappen op de schijf, het andere ziekenhuis doet dit in Excel. Er kan wel het een en ander nog verbeterd worden in Zenya, zoals snelheid van het systeem en de bruikbaarheid, maar over het algemeen wordt het gebruik van dit systeem door de gebruikende ziekenhuizen als positief ervaren. Het is een van de weinige systemen waarin workflows gezet kunnen worden.
21. Een aantal ziekenhuizen ervaren problemen met de koppeling tussen Zenya en AFAS/ Ultimo.
22. Onlangs is er bij een informatiedag vanuit AFAS ook over gesproken om het Aanschafdossier in AFAS te krijgen. Toen is er besproken dat ze hier niet mee bezig gaan, omdat elk ziekenhuis het proces anders heeft ingericht en een andere visie heeft.

Optimalisatie

23. Veel ziekenhuizen zijn constant bezig met het verbeteren en controleren van het proces. De monitoring op het proces is erg verschillend binnen ziekenhuizen, maar veel ziekenhuizen zijn

bezig met het her inrichten en continu verbeteren van deze processen. Hier gaat veel tijd en energie in zitten.

24. Niet elk ziekenhuis is bezocht door de inspectie. Sommige ziekenhuizen controleren zichzelf (vanuit bijvoorbeeld de afdeling Kwaliteit en Veiligheid) op de volledigheid van hun Aanschafdossiers.
25. Ziekenhuizen werken nog niet veel met elkaar samen op het gebied van Aanschafdossiers. Uit dit onderzoek blijkt dat mensen graag hun kennis willen delen, maar dat aangezien de processen erg verschillen dat het lastig is om samen te werken.

Toekomstbeeld

26. Er komt een nieuwe versie van het Covenant. Dit zal waarschijnlijk nog wel een aantal jaar duren voordat deze gepubliceerd wordt.
27. Door tekorten in de zorg door Corona, de oorlog in Oekraïne en energiecrisis zijn er problemen m.b.t. beschikbaarheid van (medische) producten. Hierdoor hebben inkoopmedewerkers minder tijd om te focussen op kwaliteit (van bijvoorbeeld Aanschafdossiers).
28. In de komende toekomst hebben o.a. de volgende onderwerpen invloed op Aanschafdossiers: omgaan met backorders/ alternatieven en de daarbij horende leveringszekerheid, kwaliteit van medische hulpmiddelen, evaluatie van medische hulpmiddelen, thuisgebruik van producten, duurzaamheid en informatieveiligheid. Een aantal respondenten die betrokken zijn bij het opstellen van het nieuwe convenant denken dat hier ook aandacht voor komt in de nieuwe versie.