

Aligning the work processes of the medical instrument sterilization cycle at the OLVG hospital in Amsterdam:

A holistic approach



Picture: Amex-Vienna Medical supplies and disposables

Master thesis Health Sciences

University of Twente

Faculty of Technische Natuurwetenschappen

dd Month 2017

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Preface

About 9 months ago I started this assignment realizing that this not only heralded the end of my master's program, but also the end of my student life. During this "era" I found myself fortunate enough to experience really high highs, which unfortunately always comes combined with really low lows. The epitome of this can probably be best described by my internship experience which I had during my previous master's program. During this internship, I on the one hand had the opportunity to experience life in Australia while working on a really cool project. On the other hand the time of my internship is also characterized by the unfortunate loss of my father almost exactly 2 years ago.

For once I hoped that, as closing chapter of my student life, this assignment would be smooth sailing. Little did I know that life would throw me yet another curve ball, when I saw my initial master assignment shatter on the doorsteps of the Medisch Spectrum Twente hospital. To my luck, my main supervisor Peter Schuur had an alternative option in a big city far away from "gezellig Enschede". Despite the fact that I had my doubts at first, I found myself warmly welcomed by Jan Vink (my external supervisor) and all the staff of the OLVG hospital in Amsterdam.

During my first few months I hit the ground running. I conducted interviews, wrote reports, studied literature and thought out theories. I had a good time and found that time flew past. After working on my thesis for about a good 4 months I thought that I was closing in on the finish line. I had finally managed to get permission from the exam committee to start my thesis and I found Karin Groothuis, my second supervisor, willing to guide me on my endeavor. I basically thought that I had only had to put pen to paper and that graduation was within reach.

And well.... it basically turned out that this was not the case. In that regard I now clearly understand that I underestimated the amount of effort it takes to put such an elaborate work to paper in clear and demarcated way. I therefore hope that when you read this work that you can see and appreciate the work that was put into it over the 5 months that followed.

Of course I was far from alone in achieving this final result. For this reason, and without further ado, I would like to show my gratitude and appreciation to all the people who contributed to this thesis. Especially I would like to thank my main supervisor Peter Schuur, for handing me alternatives in whatever sense, for showing patience, for coaching me through my thesis report, and for doing so with a sense of humor and a light quip. I would like to thank my external supervisor, Jan Vink, for taking me in at the OLVG, for sharing deep insights and encouraging words, but also for the light conversations, sometimes about everything and sometimes about nothing in particular.

I would also like to thank Karin Groothuis, for offering me sound advice in both number and word, for pointing out "how well I express myself in English" even though the main message is about the lacking quality of the report, and for squeezing in tightly scheduled appointments just to get the work done. I would like to thank all the staff of the OLVG and Clinium. In particular I thank Jacques Ongerboer de Visser, Dolores Healy, Erik Herder and Yvonne Pronk. I also thank my friends and family for their support and their unequalled quality to put things into perspective. And last but not least, I would like to thank Samara Abbas for her perseverance in wrestling through 100+ pages of text to help straighten out crooked paragraphs and sentences.

Management summary

This assignment was conducted in the context of completing the master of Health Sciences at the University of Twente. Here we focused on the improvement of the logistical processes which are involved in the continued usage and sterilization of reusable medical instruments at the OLVG hospital in Amsterdam. The motivation to conduct this research was that the management of the OLVG believed that the hospital can achieve significant financial and qualitative gains by equipment and work process standardization. In order to study the instrument sterilization cycle we chose to formulate the following central research question:

“What do the work processes of the instrument logistics cycle entail and what opportunities are there to optimize these processes to impact instrument storage, usage and maintenance?”

This central research question can be broken down into two distinct parts for a problem solution process. Here the first part of the question is aimed at describing the current state of the instrument supply chain, while the second part tries to establish a future image of the sterilization cycle.

To examine the current state of the instrument sterilization cycle we hypothesized that it is crucial to know a couple of things. First off we needed to know which processes are conducted by which department and we were interested to learn how these work processes are monitored. This question was answered by developing multiple flowcharts of the instrument sterilization cycle which were explained with supplementary process descriptions. Second we needed to identify the bottlenecks that cause the issues which are encountered at OLVG in order to offer possible solutions. This second part was answered by developing a gold standard for instrument sterilization management to which the current sterilization cycle was compared.

Through this gold standard comparison, we discovered that instrument flow is currently organized in a sub-optimal way due to a lack of process planning. As a first step to remedy this issue, we proposed to develop a demand forecasting model in order to give an estimate of how many instrument trays would be required to cover demand. The forecast model was built as a proof of principle for the urology department, in which the demand for a selection of urologic procedures is coupled to the demand for the corresponding instrument trays. Utilizing this model we hoped to be able to give a correct estimation of the instrument tray supplies required to cover 97.5% of all possible instrument tray demand. In the end we were able to generate a Poisson based forecast for 29 out of the 84 possible instrument tray types, with an average demand varying between 0.1 and 8.9 trays per week. Using the forecasts for these 29 tray types we were able to cover 82.38% of all possible tray demand as recorded in a 10 week training dataset, opposed to the intended 97.5%.

Forecast accuracy was determined over a separate 4 week testing dataset by means of a mean absolute scaled error (MASE). In this method a ratio is calculated between the obtained forecasting errors from our Poisson forecast method, relative to a reference forecasting error obtained from a reference forecasting method. Here a MASE smaller than 1 indicates a smaller forecast error relative to the reference error, whereas a MASE larger than 1 indicates the opposite. For our investigation we utilized an easier stochastic forecasting model over the average tray throughput in the 10 week training dataset as a reference method. Based on a calculated MASE of 0.98 +/- 0.26 for the 29 predicted tray types and a MASE of 0.63 +/- 0.55 over all 84 different tray types, we can conclude that our Poisson based forecasting model offers a forecasting accuracy equal to the more facile reference method.

Based on the overall forecasting results, we were able to conclude that this forecasting model does not offer a valid representation of instrument tray demand for all instrument tray types. By expanding the selection of the procedures which we have included to generate the forecast, however, the validity of the model can be improved. Another, perhaps more pragmatic option for accurate instrument tray demand forecasting, is to make use of past instrument tray demand to directly forecast future tray demand.

Next to the lack of a centralized instrument sterilization planning, the gold standard comparison revealed that the IT environment currently in place, is of limited use for measuring supply chain performance and thus enforcing a materials planning. This is caused by the fact that the IT environment is highly fragmented because a coherent information management strategy is currently lacking. As a secondary target for our problem solution, we therefore chose to formulate an information management strategy for the OLVG. Due to the expressed interest of the OLVG into Track and Trace (T&T), this technology should play a central role in the development of a new strategy.

In order to implement an improved version of the forecasting model, the information management strategy should include all information required to create the aforementioned forecasting model. The OLVG should therefore not only document patient centered performance and quality measures, but should also include measures for procedure demand, instrument tray demand and instrument tray throughput to facilitate demand forecasting. To accommodate this, we hypothesized that it is crucial to address the fragmentation of the current IT systems which hampers error free information documentation. If we redesign the IT environment according to this supposition, we opine that it should consist out of two systems, each covering a distinct part of the instrument sterilization cycle. Here an OR T&T system should cover all the tasks, and record all the data related to the management of instrument tray stocks. A separate EPF system, on the other hand, should be used to document all patient related information.

For the OR T&T system we also investigated which T&T technologies are suitable to facilitate its implementation. Through a literature research we were able to distinguish two possible candidate modalities being barcoding and RFID. After weighing all the advantages, disadvantages and cost considerations of the two modalities we reached the conclusion that separate instruments should be traced by the use of UDI compliant 2D barcodes whilst instrument trays can be traced by using RFID.

If we look back at the overall outcomes of this thesis a number of recommendations can be made for the OLVG. If we summarize these recommendations according to priority, the overview looks as follows:

- 1) The OLVG should at the least implement a demand forecast which allows the work process of the instrument sterilization cycle to be planned. To do so we recommend to utilize a Poisson based extrapolation of past demand data, in order to account for the variable and intermitted nature of the data. Other forecasting methodologies like moving average forecasting or normal demand forecasting have proven to cover these data characteristics insufficiently.
- 2) The OLVG should implement a more coherent IT environment which at the least monitors the patient centered performance measures and instrument quality measures coherently throughout the sterilization cycle. This is not only relevant to get an accurate view of current level, location and quality of the instrument supplies, but can also be used to enhance the accuracy of the demand forecast.
- 3) The employee stakeholders of the work processes have to be trained in operating any IT system required for their job. Furthermore, they have to be made fully aware of the importance of correct instrument tray registration.

- 4) If both a demand forecast and a more integrated IT environment are implemented, make sure that this IT environment also documents measures vital to demand forecasting. Examples thereof are measures such as procedure demand and instrument tray demand.
- 5) Instrument trays and order protocols should only be optimized and standardized with a clinical expert in the lead. In order to give direction to this streamlining process we propose to formalize the decision making process that lies at the foundation of instrument tray and order protocol compilation. Here a centralized management authority can influence the decision making process by imposing restrictions, creating incentives and empowering staff members.
- 6) Track and trace can be facilitated by utilizing RFID for the instrument trays. Separate instruments, however, have to be traced by barcodes because the RFID technology is not suitable to be used on smaller objects.

Glossary

<i>Definition</i>	<i>Page</i>
Assemble-to-order (ATO) – A type of supply chain where product components are made according to a planning and are stored before product assembly. The customer order decoupling point is located at the final assembly stage.	29
Central Sterilization Service Department (CSSD) – One of the OLVG hospital's care supporting departments, also known in Dutch as resultaat verantwoordelijke eenheden. Here the CSSD is responsible for sterilizing the used instrument tray to such a degree that they are safe to use in subsequent surgeries.	1
Critical list – A list which indicates a minimally required supply of critical instrument trays which can be used to cover unforeseen tray demand in the case of emergency surgeries.	11
Customer order decoupling point (CODP) – The point to which the customer order penetrates upstream into the production processes of a supply chain.	29
Demming Plan-Do-Check-Act cycle (Demming PDCA) – A management strategy commonly used in healthcare to elicit quality improvements. Here Plan-Do-Check-Act is continuous and repetitive process improvement strategy in which an improvement is planned, executed, checked and adjusted when necessary.	19
Electronic Patient File (EPF) – A hospital information system which documents all patient related information like patient symptoms, diagnosis, treatment schedules and surgery schedules.	12
Engineer-to-order (ETO) – A type of supply chain where product components are made according to customer order specifications. The customer order decoupling point is located at the product design stage.	29
Enterprise Resource Planning system (ERP) – A system which is utilized to conduct the resource planning of an entire organization.	13
(Order) Fill rate (FR%) – The extent to which an order is completed at the moment of delivery.	21
Global Unique Device Identification Database (GUDID) – A global database in which all medical instruments are documented and specified by utilizing UDI compliant tracing methodologies (see Unified Device Identifier).	57
Instrument repair department (IRD) - One of the OLVG hospital's care supporting departments, also known in Dutch as resultaat verantwoordelijke eenheden. Here the IRD is responsible for the repairs necessary to keep the medical instruments functional.	1

Definition	Page
Instrument trays – Metal trays that include a compilation of medical instruments which are commonly used together in one or multiple surgeries.	2
(Instrument tray) packaging slip – A list which details which instruments should be included in the instrument tray.	11
Key Performance Indicators (KPIs) – Measures to quantify the performance of a system.	5
Lead time (LT) – The amount of time between the initial order of a product and the moment of delivery.	21
Make-to-order (MTO) - A type of supply chain where products are made according to a customer purchase. The customer order decoupling point is located at the fabrication and procurement stage.	29
Make-to-stock (MTS) – A type of supply chain where products are made according to a planning and are stored before purchase. The customer order decoupling point is located at the shipment stage.	29
Mean Absolute Scaled Error (MASE) – MASE is a measure which expresses the degree of forecasting accuracy. The MASE is determined by comparing the obtained forecasting error of one method to the in-sample forecasting error of a reference forecasting method.	47
Material Resource Planning System (MRP) – A type of information system which specifies which financial, human and capital resources are required to complete a specific process step.	13
Onze-Lieve-Vrouwen-Gasthuis (OLVG) – A hospital conglomerate originating from the merger between the former Sint Lucas Andreas hospital and the former Onze-Lieve-Vrouwen-Gasthuis in 2015.	1
Operation Assistant (OA) – A medically trained professional who is responsible for nursing hospitalized patients and assisting surgeons during surgery.	2
Operation Room (OR) – A room which is prepared according to clinical safety and sterility standards which are utilized to conduct surgery related activities.	1
Process time (PT) – The time it takes to complete the specific work process.	21
Resultaat Verantwoordelijke Eenheden (RVEs) – Literally translated “Result Responsible Units” are the departments of the hospital which are either centered on care provision or care supporting tasks.	1
SD main storage – The main storage location of medical equipment and disposables which are used by the surgery department. Next to the main storage, medical equipment and disposables are stored on 12 additional (minor) storage locations across the surgery department.	8

Definition	Page
Surgery Department (SD) – One of the OLVG hospital’s care supporting departments, also known in Dutch as resultaat verantwoordelijke eenheden. Here the SD is responsible for facilitating scheduled surgeries by providing surgeons with a clean and sterile operation room, sterile and functional medical equipment, anesthesiologist support and one or more operation assistants.	1
Surgery order protocol (or Order protocol) - A list which specifies all the required disposables and reusable instruments for a specific type of surgery.	7
Surgical procedure protocol – A protocol which describes how a surgical procedure should be executed to obtain the best possible outcomes according to the most recent medical knowledge.	7
Track and Trace (T&T) – “Tracking” refers to the planning of the projected path of an item through a supply chain whereas “Tracing” refers to a reverse monitoring process of the item’s historical whereabouts.	2
Unified Device Identifier (UDI) - A medical device identifying standard which can be implemented by means of RFID or barcoding.	57
Wait time (WT) – The wait time towards the start of the process.	21

Table of Contents

Preface.....	i
Management summary	iii
Glossary	vii
Table of Contents	xi
1. Introduction.....	1
1.1. The hospital	1
1.2. The problem	2
1.3. Thesis background	3
1.4. Conclusion	4
2. Research outline	5
2.1. Breakdown of the central research question - The current state of the system	5
2.2. Breakdown of the central research question - An image of the future system	6
3. Basic concepts and layout of the sterilization cycle	7
3.1. Defining instrument trays and surgery order protocols.....	7
3.2. Defining the sterilization cycle	8
3.2.1. Detailed description of the process steps	10
3.2.2. Support systems	13
3.3. How do the issues at OLVG manifest themselves in practice	14
3.4. Conclusion	15
4. Determining system bottlenecks.....	17
4.1. Theoretical outline	17
4.1.1. The Lean methodology	18
4.1.2. Defining and using performance indicators in a supply chain control framework	18
4.2. Translating Lean into logistical policy.....	20
4.3. Evaluating the system using the Key Performance Indicators	22
4.4. Alternative performance quantification.....	23
4.5. Discussion	29
4.5.1. Specifying the scope of a proposed solution.....	31
4.6. Conclusion.....	33
5. Demand prediction model.....	35
5.1. Design considerations for a demand forecasting model.....	35
5.1.1. Implementing a forecast method in the current situation.....	36

5.1.2.	Selecting a forecasting method	38
5.2.	Generating a stochastic prediction model	40
5.2.1.	Determining the best parametric fit.....	41
5.2.2.	Building the forecasting model.....	43
5.3.	Determining the validity and accuracy of the forecast model	44
5.3.1.	Validating the forecasting model	44
5.3.2.	Determining forecasting model accuracy.....	46
5.4.	Discussion	49
5.4.1.	Covering 97.5% of the possible tray demand.....	50
5.4.2.	Influencing instrument tray supplies and demand	51
5.4.3.	General remarks	53
5.5.	Conclusion	53
6.	Devising an information management strategy.....	55
6.1.	An overview of automated track and trace in supply chains	55
6.1.1.	A brief history of automated track and trace.....	55
6.1.2.	Why allied industries adopted track and trace	56
6.2.	Addressing the pitfalls of the current IT system	57
6.3.	Track and trace selection considerations	61
6.3.1.	Weighing the pros and cons in the selection of a T&T modality.....	61
6.3.2.	Reviewing the costs and benefit considerations.....	62
6.4.	Discussion	65
6.5.	Conclusion	67
7.	Summarizing the conclusions and recommendations	69
7.1.	The current state of the system	69
7.1.1.	Describing the instrument sterilization cycle	70
7.1.2.	Pin-pointing the bottlenecks	71
7.2.	An image of the future system	72
7.2.1.	Implementing a stochastic demand forecast	73
7.2.2.	Formulating a new information management strategy	74
7.3.	Answering the central research question	75
7.3.1.	Returning to the original problem description.....	75
7.3.2.	Recommended action points for the OLVG.....	76
7.3.3.	Recommendations for future research	76

8.	References	79
9.	Supplementary material	85
9.1.	Supplement 1 – Logistics cycle of the CSSD process	85
9.2.	Supplement 2 – Expanded view of the instrument sterilization cycle	86
9.3.	Supplement 3 – Control criteria for the instrument sterilization cycle.....	87
9.4.	Supplement 4 – Amount of trays required Pareto principle	88
9.5.	Supplement 5 – Amount of trays required 90% of procedure demand.....	91

1. Introduction

In the context of completing the master of Health Sciences at the University of Twente this thesis is aimed at the improvement of logistical processes which are involved in the continued usage and sterilization of reusable medical instruments in an Amsterdam hospital. In section 1.1 we introduce the hospital and describe its organizational layout. In section 1.2 we explain the nature of the problems with which the hospital is faced. Additionally, we formulate the central research question for this thesis from the problem description provided by the hospital management. Lastly, section 1.3 provides some additional background information with respect to the hospital from regulatory and financial perspectives.

1.1. The hospital

This master thesis was conducted at the OLVG hospital in Amsterdam. The current hospital is a merged organization between the former Sint Lucas Andreas hospital and the former Onze-Lieve-Vrouwe-Gasthuis, which was initiated in 2015 [1], [2]. Here, the former Sint Lucas Andreas hospital is located on the Jan Tooropstraat in the west part of Amsterdam whereas the former Onze-Lieve-Vrouwen-Gasthuis is located near the Oosterpark in the east of Amsterdam. At present, the municipality of Amsterdam accommodates approximately 850,000 inhabitants, whilst the greater Amsterdam region accounts for an additional 500,000 [3]. In the Amsterdam municipality, the two OLVG locations form the largest general hospital with roughly 600,000 patient visits and over 55,000 admission on an annual basis [1], [2]. Next to the OLVG there are five other hospital conglomerates and various specialized or outpatient clinics that are currently operating within the municipality area [4]. Among these hospitals are the MC Slotervaart and BovenIJ general hospitals which provide similar services in a similar service area compared to the OLVG. The specialized cancer center Antoni van Leeuwenhoek and the AMC and VuMC academic medical centers on the other hand also draw patients from a wider area given the increased complexity of the provided care [5]. In the greater Amsterdam region, additional hospitals can be found in Amstelveen and Purmerend [4].

The OLVG is governed according to a model in which the Board of Directors bare the primary financial and operational responsibility of the hospital [1], [2]. The board of directors are supported by several supervisory bodies of which the Advisory Board is one of the most important. Parts of the operational responsibilities are delegated to so-called “Resultaat Verantwoordelijke Eenheden” (RVEs). These RVEs are oriented to facilitate either care centered or care supporting processes. Examples of care centered RVEs are the emergency ward RVE or specialist department RVEs like the cardiothoracic surgery department, the urology department, and the neurology department [1], [2]. Examples of care supporting RVEs on the other hand are the hospital pharmacy, the radiology department, the intensive care unit, the central sterilization services department and the surgery department. During the merger, both hospitals have retained most of their care supporting RVEs together with their emergency wards and intensive care units to facilitate 24/7 acute care. The respective specialist departments, however, are or will be relocated to either of the hospitals based on strategic choices for the distribution of elective care over the two locations.

1.2. The problem

This thesis focusses on a flow of reusable medical instruments between three of the OLVG care supporting RVEs, being the surgery department (SD), the central sterilization service department (CSSD) and the instrument repair department (IRD) of OLVG location East. The main responsibility of the SD is to facilitate scheduled surgeries by providing surgeons with a clean and sterile operation room (OR), sterile and functional medical equipment, anesthesiologist support and one or more operation assistants (OA). Between the SD and the other two RVEs a closed loop supply chain is formed to ensure that the SD is always provided with functional and sterile instruments [6]. Here the main task of the CSSD is to sterilize used medical instruments as fast as possible in order to avoid instrument shortages for subsequent surgeries. The IRD takes care of all repairs that need to be conducted to keep the reusable instruments functional and safe. Complicated repairs are outsourced to the manufacturer whilst simple repairs can be done on site.

At present the merger of the two hospitals has entered its final phase in which departments, processes and (financial) resources are merged, adjusted and standardized. During this phase, a significant variance has been found in the way that the instrument sterilization cycles have been organized over the two hospitals. When looking on a macro level it can be observed that the former Sint Lucas Andreas hospital chose to centralize all hospital and outpatient related CSSD activities on the Jan Tooropstraat location. In contrast, the former OLVG has opted for an outsourced CSSD facility to mitigate the spatial constraints that became apparent, following a rise in the demand for surgeries. This outsourced CSSD facility is operated by an external partner company called Clinium, which has expanded its operations to other hospitals since it was established some 15 years ago. With the merger of the two hospitals a choice has to be made whether to continue the in-house CSSD activities of the former Sint Lucas Andreas for the entire OLVG, or to expand the outsourced services of Clinium.

On a micro level, variance can be observed in the usage, cleaning and maintenance of the surgical instruments, which are distributed over an estimated 5000 surgical kits for the entire OLVG. These kits are prepared in paper wrapped metal baskets which are called instrument trays in the clinical practice (picture 2). With the merger of the specialist departments it became apparent that the hospital's SDs frequently order different instrument trays or differently composed instrument trays in order to conduct the same surgery. In turn this is supposedly caused by utilizing different clinical procedure protocols as a result of varying specialist preferences [7].

At present the operational management of the OLVG believes that the hospital can achieve significant financial and qualitative gains. This is to be achieved by merging and standardizing the instrument kits of both hospitals, and by reducing their respective handling times in the sterilization cycle. The possibilities for doing so are currently investigated by the CSSDs and SDs of both locations. From the OLVG East SD's perspective a masters assignment was formulated which focusses on the optimization and standardization of the work processes involved in the instrument sterilization cycle. The original problem description covered three areas for which both quantitative and qualitative deliverables were desired. In short the three areas can be described as follows:

- 1) The SD wanted to know in which way the instrument tray supply chain should be improved in order to reduce the amount of instrument trays.
- 2) The SD was interested to learn which opportunities there were to support and improve quality control by implementing Track and Trace (T&T)

- 3) The SD wanted to know how instrument tray contents can be streamlined in short term, to achieve qualitative gains and to reduce the amount of instrument sterilizations.

In relation to these formulated problems the SD hypothesized that the main challenge in finding an answer to either of these problems would be to find coherent performance related quantitative evidence. According to the SD the OLVG is currently insufficiently aware of the overall performance of the instrument sterilization cycle and of the inventory positions of all the supplies in the chain. This is supposedly caused by the fact that hospital management has a limited view of how the work processes are conducted and how the sterilization cycle is monitored throughout all the departments that are involved. At present all quantitative data is recorded and processed by fragmented IT systems which only communicate with each other to a limited extent. Because of the inherent complexities involved in the problem description we assumed that a fundamental analysis would be appropriate to describe the current state of the instrument supply chain and to identify which aspects deviate from an ideal situation. To come to a most satisfying answer to the problem description above, the following research question was formulated:

“What do the work processes of the instrument logistics cycle entail and what opportunities are there to optimize these processes to impact instrument storage, usage and maintenance?”

The scope of the research was narrowed down further by looking at a single specialist department, in this case the Urology department located in OLVG East. This department was selected because it makes use of a relatively limited variety of instruments. Furthermore, as of March 1st 2017 the Urology department is one of the few departments which have been fully transferred to a single hospital location. This was done because it significantly reduces the complexity of tracing single instrument trays through the hospital logistics system. Going from the conclusions for the Urology department more generalized ideas were generated in an attempt to impact the instrument supply chain for the entire organization.

1.3. Thesis background

The OLVG merger on its own is not a particularly isolated event. As outlined in section 1.1 the OLVG has to contend with significant competition in the second line health care market in Amsterdam. In this market, the MC Slotervaart and BovenIJ hospitals are organizations that already result from hospital mergers in an attempt to restructure second line health care in the second half of the 20th century [8], [9]. The AMC and VuMC academic hospitals on the other hand are also exploring the possible benefits of a merger [10]. To understand the reasoning behind this merger tendency we also have to observe the regulatory and financial perspectives that govern modern healthcare. With the introduction of the national health insurance laws in the 1940s and 1950s, Dutch healthcare expenditures became a collective financial responsibility [11], [12]. Similar to the global trend, the burden of this financial responsibility demonstrated a sharp increase over the following decades due to the increased consumption of healthcare. To curb these increases, various payment models have been developed worldwide, varying from fee-for-service to lump-sum budgeting models and numerous hybrids between the two [13].

With the most recent overhaul of the Dutch health insurance system, the Dutch government introduced a fee-for-service primed payment model which included a competitive element labelled “market driven competition” or “marktwerving in de zorg” [12]. Whilst the legitimacy of this label is debatable, the legislation stimulates care providers to compete with each other to offer the highest quality care for the most attractive price per treatment unit. As a consequence of the competitive environment and the ever persisting rise of healthcare expenditures, care providers are prompted to intervene with increasingly drastic measures on both strategic and operational levels to improve their effectivity and efficiency [14].

Here operational up-scaling, for example by merging with a similar organization, is a textbook example to achieve cost-reductions because it allows the organization to distribute its overhead costs over a significantly larger production base [15]. Moreover, up-scaling allows for higher degrees of specialization within a care providing organization because both financial and material resource consolidation could ensure a more solid return on investment [5], [16]. Next to these internal benefits, up-scaling by merger also results in external benefits. Because larger health care providers cover a larger segment of the health care market, these organizations can obtain more beneficial negotiation positions with respect to health insurers and equipment suppliers alike [16], [17].

1.4. Conclusion

This master thesis is aimed at the improvement of the logistical processes that are involved in the continued usage and sterilization of reusable medical instruments in the OLVG hospital in Amsterdam. The current hospital is a merged organization between the former Sint Lucas Andreas hospital and the OLVG. As a result of the merger an existing variation in clinical practice became evident within the work processes. This variance also affects the processes involving the usage, cleaning and maintenance of surgical instruments which are distributed over an estimated 5000 surgical instrument trays. At present the hospital management believes that significant financial and qualitative gains can be achieved by merging and standardizing the processes involved in maintaining the instrument trays of both hospitals. From the SD's perspective a masters assignment was formulated which focusses on the optimization and standardization of the work processes involved in the instrument sterilization cycle of OLVG East. Because of the inherent challenges posed by the problem description of the SD, the following research question was formulated:

“What do the work processes of the instrument logistics cycle entail and what opportunities are there to optimize these processes to impact instrument storage, usage and maintenance?”

2. Research outline

In this chapter the research framework of the thesis is explained. In essence the central research question formulated in section 1.2 can be broken down into two parts, each of which can be captured in two sub-questions. The first part of the question is aimed at describing the current state of in the instrument supply chain, which is broken down in section 2.1. The second part on the other hand tries to establish a future image of the sterilization cycle and is described in section 2.2.

2.1. Breakdown of the central research question - The current state of the system

To examine the current state of the instrument sterilization cycle we hypothesized that it is crucial to know a couple of things. First off we need to know which processes are conducted by which department and we would like to learn how these work processes are monitored. This is captured in sub-question 1. Here sub-questions 1a and b are answered by establishing the basic layout or “ground form” of the separate work processes that together make up the instrument sterilization cycle [18]. This graphic layout is presented in the form of a flow chart which is based on the qualitative input from ethnographic observations and stakeholder interviews. In addition a list is included of the employee stakeholders and the IT support systems involved in each of the process steps. Question 1c on the other hand will be answered by providing a brief account of how the in chapter 1 mentioned issues manifest themselves in practice. This will be based on the observations and interviews as well.

1) *What work processes does the overall instrument supply chain entail and how are these processes monitored from a holistic perspective?*

- a) *Which work processes are conducted by which of OLVG RVEs and who are the employee stakeholders involved?*
- b) *By what means is the performance of the sterilization cycle monitored in order to manage the overall work flow?*
- c) *How do the issues, explained by the SD in section 1.2, manifest themselves in practice?*

Second we need to identify the bottlenecks that cause the issues uncovered by sub-question 1c in order to offer possible solutions. To do so, we want to gain a principle understanding of what a gold standard for supply chain control should look like in order to pin-point the issues of the current sterilization cycle in an assessment. This is covered by sub-question 2. In short the gold standard will be drafted by performing a literature investigation into supply chain control. Based on the problem description in the previous chapter we hypothesize that the generation of an efficient and effective work flow will be our highest priority. In order to do so we deem the Lean methodology the best suited to function as our foundation strategy for the supply chain [19], [20]. Based on the methodology we will formulate flow related Key Performance Indicators (KPIs) which are used quantify the performance of the sterilization cycle from a Lean perspective. The findings following from the comparison between the current sterilization cycle and the gold standard will be discussed in an assessment report in order to generate possible solutions.

2) *What are the bottlenecks in the current instrument sterilization cycle from a fundamental design perspective and how should they be resolved?*

- a) *How should supply chain control be organized from a theoretical and Lean based perspective?*
- b) *Which performance indicators should be used in organizing such a supply chain?*
- c) *To what extent is the organization of the current sterilization cycle in agreement with theoretical gold standard?*

- d) *In what way should we alter the current sterilization cycle in order to create a more reliable and predictable flow of instruments?*

2.2. Breakdown of the central research question - An image of the future system

As explained in section 2.1 our goal will be to enhance the work flow in the current process chain. To generate an image of the future state of the instrument sterilization cycle we should therefore address the main flow disturbing factors that were observed in answer to sub-question 2. As suggested in sub-question 2d we believe that the predictability of a variable instrument demand might play an important role in creating a reliable instrument tray flow. We will therefore investigate whether demand forecasting might have a beneficial impact on the flow of instrument trays through the sterilization cycle. This is captured in sub-question 3. In short a forecasting methodology will be introduced in a separate chapter where we will focus on how the methodology works, how it will impact the logistical ground form and how it can be utilized for correct tray and order protocol compilation.

3) *In the context of the urology department and in a general context, how can demand forecasting be utilized in order to reduce the amount of inventory?*

- a) *How does demand forecasting impact the flow of goods and information relative to the “ground form” established in answer to sub-question 1?*
- b) *Which forecasting method should we use and how should a forecasting model be built?*
- c) *How can surgery order protocol and instrument tray compilation be impacted by the implementation of demand forecasting?*

A forecasting model as proposed in answer to sub-question 3 can only work under the assumption that other preconditions in the instrument supply chain are optimally organized. One important prerequisite is that all work processes are supported by an adequate information management system. For this thesis we will therefore have to investigate whether the current IT environment is geared towards measuring the right data in order to provide correct information at the right place and time. This topic is covered by sub-question 4. Sub-question 4 will be answered in a separate chapter by drafting a design proposal for an improved IT environment. This proposal will be generated by examining the information flows that will be necessary to support the demand forecasting model as proposed in answer to sub-question 3.

Because the OLVG voiced an explicit interest into the incorporation of T&T in such an IT environment, this specific technology will have to play a central role in the redesign of the IT environment. We will therefore have to include a literature study in which we will investigate how a T&T works and which technologies would be available in order to facilitate the sterilization cycle. We therefore plan to retrieve articles from *Scopus*, *ScienceDirect*, *Springer* and *Google Scholar* databases using a combination of the following keywords; *Barcode*, *RFID*, *UDI*, *Implementation*, *resource management* which are applied in several industries: *food*, *pharmaceutical*, *healthcare*, *automotive*, *aviation*.

4) *Which IT improvements and which Track and Trace technologies need to be considered to cement the aforementioned demand forecast into the clinical practice?*

- a) *What information is required to properly control the sterilization cycle and from which IT systems should this be obtained?*
- b) *Which Track and Trace technologies are suitable to be implemented to gather the data required by the IT monitoring systems?*
- c) *Which considerations need to be made in the selection and implementation of these Track and Trace technologies?*

3. Basic concepts and layout of the sterilization cycle

In section 2.1 we concluded that we need to gain a deeper understanding of how the sterilization cycle functions and what the underlying problems are that play a role in the case of the OLVG. Let us first try to define the basic concepts and definitions that are crucial in the understanding of the sterilization cycle in order to answer sub question 1. This knowledge can then be used to expand upon during the rest of the thesis. In section 3.1 we explain what instrument trays and surgery order protocols are. Section 3.2 follows up by explaining how these instrument trays and order protocols are used in the sterilization cycle. This is done by providing a layout of the work processes of the instrument sterilization cycle and by providing an outline of the IT systems involved in monitoring the instrument sterilization cycle. Lastly we explain how the problems described in section 1.2 manifest themselves in the clinical practice in section 3.3.

3.1. Defining instrument trays and surgery order protocols

In modern hospital settings surgeries are conducted with a wide variety of tools that are adjusted for a specific task [21]. These tools can consist of disposable items like suture material or bandages, larger machines as X-ray or laser equipment but also of smaller reusable instruments like endoscopes, surgical scalpels, clips or tweezers. To make sure that all the required instruments and disposables are available at the start of a surgery, these tools are ordered in advance from a sterile warehouse according to a surgery order protocol (picture 1). Here a surgery order protocol is a list which specifies all the required disposables and reusable instruments for a specific type of surgery.

For some surgeries, up to 50 or more reusable instruments may be required over the course of the procedure. In order to make the collection of these items less laborious, instruments that are commonly used together can be pooled in metal trays called instrument trays (picture 2). Using instruments pooled in trays also allows for important safety benefits. First of all, all instruments have to be counted and accounted for both before and after surgery which is made easier by grouping them into known quantities. This counting is of paramount importance because instruments lost inside surgical wounds are a serious health and safety issue for patients [22]. Additionally, instruments pooled in instrument trays allow for easier monitoring with respect to qualitative or functional defects.

At OLVG Instrument trays and surgery order protocols are compiled and reorganized per surgical specialty by an appointed OA instrument specialist. These trays and protocols are predominantly based on the surgical procedure protocols which describe how a given surgical procedure should be executed according to the best surgical practice guidelines. Sometimes these surgical practice guidelines allow for some room for interpretation for the surgeon conducting the procedure. In these cases surgeon preference can be decisive in how the guidelines are interpreted which leads to minor variations in surgical procedure protocols and thus in slight variations in surgical order protocol or instrument tray composition for a single procedure.

When a surgical procedure protocol is altered the OA instrument specialist determines which functionalities are required from the medical instruments. This change in functional requirements may result in some instruments becoming obsolete whilst other additional instruments might be required to fulfill new functional requirements. For example, if an invasive surgery is being replaced by a laparoscopic type of surgery, in theory most of the incisive instruments can be removed and endoscopic based instruments can be added. The difference between (re)organizing instrument trays and order protocols lies in the frequency at which these processes are conducted. Instrument trays can be used to serve a relatively wide variety of surgeries and include only reusable instruments. As a consequence they are

reorganized at a low frequency and at random time intervals. In practice this means that for a change-sensitive specialty like orthopedics, 10 tray types were reorganized over the year 2016. Order protocols on the other hand are specific for each surgery. Next to the required instrument trays they also include a broad variety of disposables and implants from multiple manufacturers. These protocols are therefore changed with a relatively higher frequency than instrument trays.



Picture 1. An example of a completed order of disposable items and reusable instruments which will be used for surgery. This order was compiled on a surgery procedure cart according to a surgery order protocol. The protocol is included in the second drawer.



Picture 2. An example of an instrument tray. The compilation of instruments was placed in a metal tray for the pooling advantages described in section 3.1. During storage and transport these trays are wrapped in specially designated paper wrappings to avoid contamination.





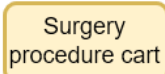
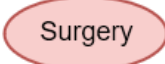




3.2. Defining the sterilization cycle

Now that we defined instrument trays and surgery order protocols we can investigate how these are used in practice. In general terms the instrument sterilization cycle of OLVG East can be visualized as done in figure 1. In essence, the logistics cycle is a stream of supplies which moves through various internal and external departments which all influence the quality of the end product through their internal processes.

From left to right top and to bottom the following steps can be observed. All instrument trays that can be used for a surgery are stored in the surgery department main storage (SD main storage). From the SD main storage, instrument trays are loaded on to surgery procedure carts together with disposable instruments according to the surgery order protocols. In most cases these trays will be used during surgery after which they will undergo a quantity and quality check. During these checks it will be determined which instruments can enter the sterilization cycle directly (visualized in supplement 1) and which instruments require repairs. Unused instrument trays are returned to the SD main storage.

Except for instrument repairs and instrument sterilization all the aforementioned steps fall within the SD sphere of influence. For OLVG East, instrument sterilization is carried out by Clinium, which is an external Centralized Sterilization Services Department (CSSD) company located in the greater Amsterdam municipality area. Faulty instruments on the other hand are repaired by the Instrument Repair Department (IRD) or are replaced by the SD. The consideration of repair versus replacement is done based on the nature of the defect, the estimated cost of repair and the estimated cost of instrument replacement.

Table 1. Legend for the flowcharts used to represent the sterilization cycle during this thesis report

Symbol	Meaning
	Instrument tray flow
	Reusable instrument flow
	System information flow
	Monitoring system
	(Storage) location node
	Activity node
	Decision node
	Scanning activity
	Outbound order
	Inbound delivery

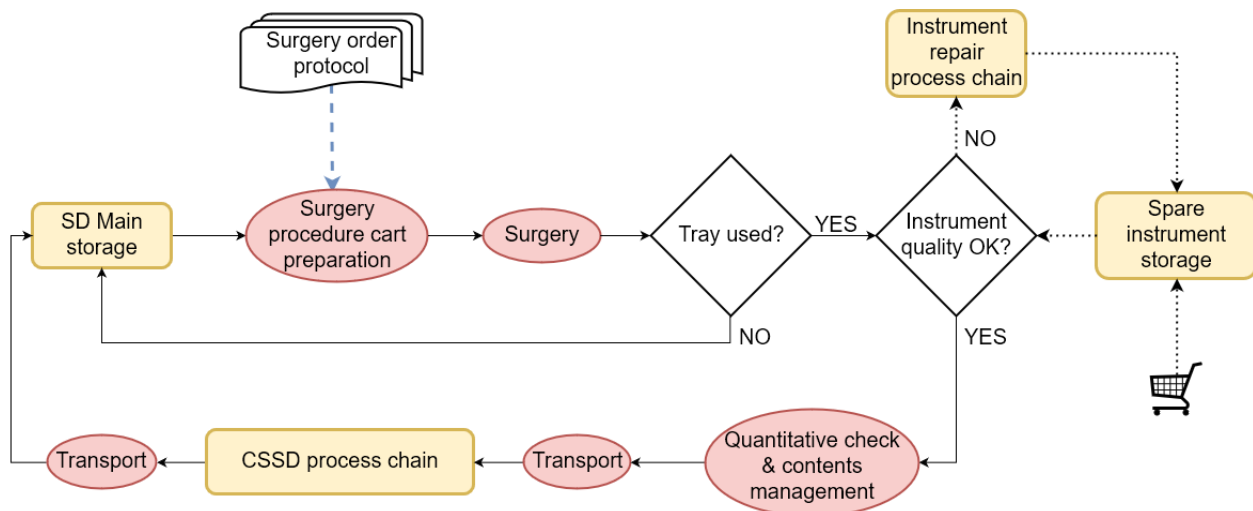


Figure 1. General layout of the logistics cycle for reusable medical instruments. The direction of the arrows indicates the direction of the stream. When looking at “SD main storage” versus “CSSD process chain” one can say that the “SD main storage” lies downstream of the “CSSD process chain” or that the “CSSD process chain” lies upstream of the “SD main storage”.

3.2.1. Detailed description of the process steps

Now let us zoom in on the separate steps to determine what actually occurs during these steps and which employee stakeholders are involved.

SD main storage - Roughly speaking the SD storage room is divided into three parts, an instrument tray repository, a disposables repository and a disposable tray repository. Here disposable trays, similar to instrument trays, are trays of disposables which are packaged together by suppliers because of pooling advantages. All shelves are replenished and depleted according to the First-In-First-Out principle to avoid unnecessary product expiry. This means that depletion occurs from right to left, top to bottom and front to back whilst stocking is done in the exact opposite direction. Besides the main storage, the SD stores reusable instruments, surgical medication and disposables on 12 other locations throughout the department due to lack of space in the main storage. Each morning all supplies are restocked by the SD logistics employees which can take up to 60 minutes depending on the amount of supplies ordered from Clinium or the respective disposable suppliers.

Surgery procedure cart preparation – In the morning the surgery order protocols for the following day are provided to the SD logistic employees for order picking. Each protocol is double checked by hand before collecting for the surgery order. This is done because the surgery schedule is subject to continuous changes. During order picking all surgery materials are loaded on one or more surgery procedure carts per OR, depending on the complexity of the planned surgeries. Generally speaking, cart loading occurs through an informal agreement that all bulky disposable trays go on top of the cart followed by instrument trays and unbound materials ordered per surgery (picture 1). Because of the dispersed nature of instrument storage as explained earlier in this section, order picking is conducted in two stages. First the supplies are collected from the SD main storage room after which the remaining items are collected from other storage rooms. When a procedure cart is completed the cart is transported from the initial holding in the SD storage room, to the supply niches next to the respective Operation Rooms (ORs).

Next to the surgery order protocols the warehouse team also has to work with a critical items list and emergency calls. Here emergency calls are used to communicate an urgent need for additional items for surgeries that have already started or are soon to start. The critical items list indicates a minimally required supply of critical instrument trays which can be used to cover unforeseen tray demand in the case of emergency surgeries. If the supply of critical items runs low or if the supply of regular items is depleted, the items in question are not added to the procedure cart and a rush order is forwarded to the Clinium CSSD by email.

Surgery - At the start of the day the OAs transport the surgery procedure carts from their respective niches into the ORs for preparation. The exact timing of instrument preparation with respect to the surgery varies according to the surgery complexity and the preference of the OA. In the case of more complex surgeries in general, the required instruments are opened and scanned in the OR preparation room prior to usage. As a consequence some of the opened items remain unused and are disposed of unnecessarily. For smaller surgeries the instruments are unpackaged and handed to the surgeon on request.

Most instrument trays do not have an internal priority arrangement which indicates in which order the instruments should be used (picture 2). This is due to the size and shape of the instruments and because of the fact that the trays might be used for multiple procedures. Therefore the OA arranges complex instrument trays according to the sequence of events which are typical for the procedure at hand (picture 3). When the instruments are unpacked and prioritized they are counted and compared with the packaging slip which is included with the tray. Missing items are marked on the slip and are subsequently reported to the CSSD department. Additionally, the instrument labels are removed from the packaging and are placed on a designated procedure sheet. After the surgery, all labels on the procedure sheets are scanned and linked to the treated patient in an OR Tracing system. In this way the SD can keep track of instrument usage per patient which is predominantly done for recall purposes.



Picture 3. A demonstration of the pre-surgery preparation of an instrument tray conducted by an OA.

After the surgery has been concluded, all used instruments are counted and checked again with the (updated) packaging slip to make sure no instruments went missing. Used instrument trays are subsequently transported to a processing room to undergo a final quality and quantity check (see **tray check and contents management**). All unused instrument trays are returned to the SD storage room.

Tray check and contents management – As described before in the introductory chapter (1), the OLVG has outsourced all its sterilization activities to an external company called Clinium. Because this company is located at a significant distance from the hospital location, it is crucial to determine if all medical instruments are accounted for after surgery to ensure patient safety. Clinium has therefore stationed a designated Clinium employee at the OLVG hospital who is responsible for checking all instruments prior to shipment. During the tray check and contents management the Clinium employee weighs all instrument trays to double check if all instruments have been replaced on the trays. If this is not the case a root cause investigation will be started to ascertain if, where and why an instrument went missing. If the instrument is not found in the investigation it will be replaced from the spare instrument repository. In addition to a quantitative check, the Clinium employee performs a qualitative check as well. If any of the instruments showed functional defects during surgery they are reported by the OAs for a closer inspection. If these instruments cannot be mended by the Clinium employee through simple repairs, malfunctioning instruments will be replaced with instruments from the spare instrument repository.

Complete instrument trays with functional instruments are registered to transport carts. Because Clinium CSSD delivers instrument trays on five occasions per day (Figure 1 Transport to SD main storage), these transport carts are returned to the CSSD facility with the corresponding delivery trucks (Figure 1 Transport to CSSD).

Spare instrument storage and instrument repair – Defective or missing instruments are replaced from the spare instrument storage by the dispatched Clinium CSSD employee. Malfunctioning instruments are gathered once a week by an OA quality employee who will determine if the instrument should be discarded or mended at a specialized hospital department for instrument repairs. This decision is predominantly based on the cost estimates of buying a new instrument versus the costs of repair. Item repair usually takes one week after which they are returned to the storage. New instruments are ordered manually when the instrument of interest has been depleted from storage, or if new instruments are requested for a changed surgery protocol.

CSSD process for used trays – In the sterilization cycle (supplement 1), the reusable instruments are sterilized according to a specific sequential procedure in which they are prioritized, washed, inspected, wrapped, sterilized and transported back to the hospital. Between these steps the instrument trays are scanned to obtain information on how the specific tray should be handled during the next CSSD process step. Additionally these scans serve as a tracking signal to the software system which monitors the stage the tray is currently in. Once sterilization is completed the trays are moved to the final stage where a sterilization process check is conducted. If the sterilization process has satisfied the requirements, the trays are scanned for completion and moved to the sterile holding for transport. The corresponding costs for sterilization are added to a monthly invoice. If the sterilization process was not satisfactory the trays are returned to an earlier stage to repeat the process.

3.2.2. Support systems

To facilitate and coordinate the instrument logistic cycle, information systems play a prominent role. Within the current organization of the logistics cycle there are five software systems that will all be described briefly in this section.

In short the processes in the sterilization cycle are monitored by an Electronic Patient File system, an Enterprise Resource Planning system and three partial tracing systems. Here the Electronic Patient File system, or EPF, is a system which documents all patient related information [23]. Important examples thereof in the context of the instrument supply chain are the documentation of scheduled surgeries and the surgery order protocols. The Enterprise Resource Planning system, or ERP, is defined as the system which is utilized to conduct the resource planning of an entire organization [24]. From a historical perspective ERP systems have evolved from Material Requirements Planning (MRP I) and more advanced Manufacturing Resource Planning (MRP II) systems which specify the financial, human and capital resources that are required to complete a process step. Originally MRPs only covered the needs of single departments but as manufacturing processes became increasingly complicated the need to coordinate activities over multiple departments grew, prompting the development of ERPs as an IT based solution [24]. In the OLVG, the ERP covers mostly financial management functions. In the logistics cycle this system is responsible for managing a limited part of the process flow. As such the ERP is used to keep track of the current stock positions for disposables and for manually ordering new instruments when stock levels become critical compared to minimum references levels. Because the aforementioned systems cover only a limited extent of the required functions the OLVG uses three IT support systems with limited tracing capabilities.

- 1) At present the SD utilizes a Copernicare OR tracing system, predominantly to monitor trays on expiration and utilization per surgery. Here the latter functionality is one of the decisive features for which the OR tracing system was implemented in OLVG East. The utilization registration serves to couple the instruments and implants to specific patients for recall purposes, a feature which was overlooked in the current EPF system.
- 2) Clinium and CSA West both make use of privately developed CSSD track and trace environments. These systems allow for detailed instrument tracking throughout the entire CSSD cycle in terms of tray location and tray contents. In addition it allows for detailed tracing with regards to cleaning history, cleaning lot numbers and tray mutations.
- 3) Lastly the IRD makes use of an instrument repair tracing system called Ultimo. The tracing system is used to document repair details, supplier contacts, repair related expenses and repair frequency for instruments that are kept in small quantities. These are usually instruments that also represent a high monetary value. Repair information for instruments that are kept in large quantities are documented manually or not at all.

If these information systems are knitted into the general layout of the logistics cycle, the previous flowchart (figure 1) can be expanded to the flowchart depicted in figure 2. An enlarged version can be found in supplement 2.

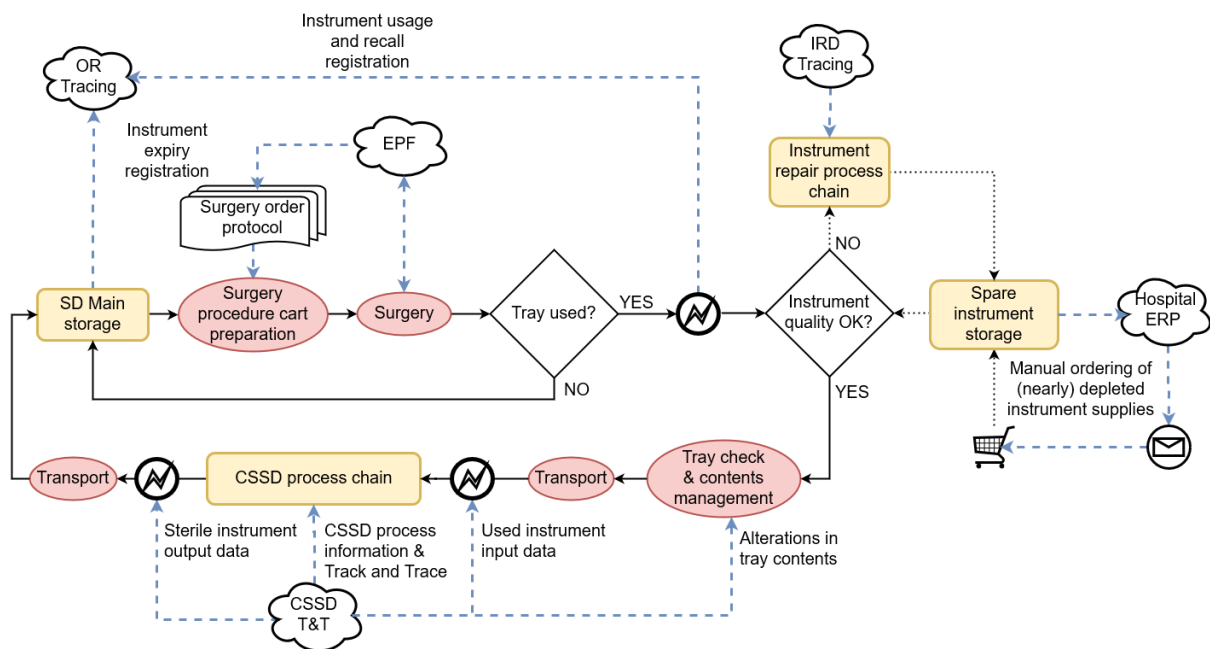


Figure 2. The expanded logistic cycle for reusable instruments. Note that there are five different IT systems making up the overall IT environment for the instrument sterilization cycle.

3.3. How do the issues at OLVG manifest themselves in practice

After the interviews and observations have been conducted, it became apparent that OLVG East has problems managing the current supply levels necessary to meet surgical demand. As mentioned in section 3.2.1 the SD maintains 12 additional storage locations next to the SD Main storage due to the spatial constraints of the main storage. As a consequence of this dispersed storage of supplies, the collection of instruments and medication according to the surgery order protocols becomes a more complex and time consuming task to complete. Inherent to the increased complexity is the additional risk of errors in the correct completion of the surgical orders.

Apart from the issues involving the work processes, the current supply warehouse design also poses a threat in terms of health and safety of patients. This is because the current SD main storage could not be located in the OR complex due to its size. As a consequence, sterile supplies have to be transported through a non-sterile environment to reach the OR. This effect is exacerbated by the fact that the unused supplies are returned to the sterile main storage from a non-sterile OR following the same non-sterile route by which the instruments were delivered in the first place. Both the location of the main storage, as well as the fact that unused instruments are returned to the sterile storage, have therefore been labeled as “undesirable” according to the hospital’s infection prevention department.

What remains unclear, however, is the question if these phenomena are simply caused by a lack of space, or if this is due to overstocking. According to an analysis report generated by Clinium CSSD in August of this year, OLVG East currently makes use of roughly 500 different instrument trays types of which 1000 are kept in storage. Until the start of our current investigation, however, the OLVG lacked the means to determine where these stocks reside in the sterilization cycle and if these amounts are sufficient to cover

tray demand. These issues will therefore have to be one of the main targets in the search for a possible solution.

In contrast to the amount of instrument trays, the amounts of single instruments (not bound to an instrument tray) still remains to be determined. As explained in section 3.2.1 the replenishment of spare instruments for OLVG East is not conducted in a coordinated fashion. New instruments are manually ordered when stocks have been depleted or when new instruments are required for a new surgery protocol. This was originally caused by the fact that up until this year every surgical specialism managed their own spare instrument supplies. With the start of this year the responsibility has been transferred to one OA working under SD management supervision. Because of the recent shift from a disperse to a consolidated management approach, it is unknown what the exact inventory levels are and whether or not the inventory matches the contents of the maintained instrument trays. To solve the supply uncertainty, the OLVG has not launched one, but two stock taking initiatives. Surprisingly, these initiatives are separately coordinated for both OLVG East and West.

The last thing that we want to highlight is the relatively high uncertainty in the compilation of surgical procedure carts. As explained in section 3.2.1 surgery procedure carts are compiled according to surgery order protocols. In turn these protocols are dependent on the surgery schedules that have been established for the following days. What we have observed in practice is that these surgery schedules are frequently changed up to the last possible moment. Constant double checking of the order protocols has therefore become a crucial part of the daily practice for the SD logistics employees, adding to the work load and job complexity. Furthermore, we suspect that this high degree of variability could also lead to the use of over complete surgery ordering protocols to account for the instruments that might be required “just in case”.

3.4. Conclusion

In this chapter we have established the basic definitions of surgery order protocols and instrument trays in section 3.1. In section 3.2 we outlined the basic layout or “ground form” of the instrument sterilization cycle which can be observed in figure 2. The description of the work processes in this cyclic supply chain can be summarized as done in table 2. Next to the separate process steps the table lists the respective employee stakeholders and IT support systems involved in conducting each of the process steps. In section 3.3 we explained how the problems described in section 1.2 manifest themselves in practice. Especially the hospital’s inability to store and manage the large amounts of instrument supplies required for the surgeries became apparent. On a first glance, we were not able to determine if this is simply caused by a lack of space, or if this is due to overstocking. Furthermore, we highlighted the fact that the compilation of surgery procedure carts is subjected to high degree of variability originating from the surgery schedules.

Table 2. A summary of the work processes of the instrument sterilization cycle.

Department	Activity	Employee stakeholder	IT system
SD	Surgery procedure cart preparation	SD logistics employees – Compiling surgery procedure carts, restocking the OR storage rooms, (rush) ordering medical instruments from suppliers/CSSD and fulfilling rush orders from the ORs	EPF – Provides the surgery order protocols according to the surgery schedule
SD	Surgery	OAs – Preparing instruments for usage, assisting the surgeons, counting all instruments and disposables before and after surgery and documenting instrument usage in the OR Tracing system (Surgeons – Performing the surgery and documenting all the surgery specifics in the EPF)	EPF – Documents patient specific details OR Tracing system – Documents instrument usage for recall purposes
SD/CSSD	Tray check and contents management	(Dispatched) CSSD employee – Performing all contents checks and content mutations for the instrument trays Instrument specialist OAs – Determining instrument tray contents and content mutations based on the Surgery procedure protocols	CSSD T&T – Documents and tray contents and content mutations
IRD	Instrument repair process	IRD employees – Facilitating all repair related processes for reusable instruments and documenting the respective repair details	IRD Tracing system – Documents repair details of expensive low volume instruments
CSSD	CSSD activities	CSSD employees – Facilitating all CSSD related processes for the instrument trays	CSSD T&T – Monitors sterilization quality, process progress, batch numbers, tray composition etc.

Note that because the ERP system is only used for manual ordering of depleted stores and for financial purposes, that the system is not really involved in the core processes of the supply chain. Furthermore, we can conclude that the surgeons are only sidelong involved in the sterilization cycle because all the necessary rooms, staff and equipment will be provided to them for a surgery and does not require their direct involvement.

4. Determining system bottlenecks

In chapter 3 we have described what instrument trays and surgery order protocols are. Furthermore we described what the work processes entail and what their basic layout looks like in the instrument sterilization cycle. Last, we have also described in section 3.3 how the problems described in chapter 1 manifest themselves in practice. Now that we have familiarized ourselves with the full scope of the problem case, we can shift our focus to identifying the bottlenecks of the sterilization cycle in answer to sub-question 2.

To do so we would first have to obtain a principle understanding of how supply chains should be organized from a theoretical point of view. Section 4.1 therefore provides a theoretical outline on how supply chain management can be utilized to solve supply control issues. Moreover, this section will delineate how performance measures should be defined in order to measure supply chain performance and reflect on possible solutions. Because the theoretical ideas are taken from a general supply chain context, they will have to be translated for application in a clinical context. This is done in section 4.2. In sections 4.3 and 4.4 we continue by investigating whether or not these performance measures can be obtained from the current IT support systems that monitor the instrument sterilization cycle. Last, in section 4.5 the results of this chapter are discussed to determine the bottlenecks in the current system and identify the opportunities for improvement in answer to sub-question 2.

4.1. Theoretical outline

In this section we provide a theoretical outline of how supply chain management should be applied to solve the most pressing issues at OLVG. From literature we can deduce that supply chain managers can be faced with two types of problems when organizing supply chains: design problems and control problems [25]. Here design problems refer to the organization of the core processes that are involved in the logistical chain. Changes that are made in answer to design problems are therefore reflected by alterations in the basic layout of the work processes, such as the one depicted in figure 2. Control problems on the other hand, refer to how the current work processes are managed without affecting the basic layout. Changes made with regard to control problems usually involve measures like altered process planning and improved process alignment. For this thesis we have chosen to approach the issues at OLVG from a supply chain control perspective. This was done because proper supply chain control is fundamental to the correct execution of work processes in the supply chain [18]. If the problem cannot be solved by approaching the current issues from a control standpoint, additional investigation can focus on a (re)design approach where we hypothesize that the implications for the sterilization cycle are likely to be more profound compared to alterations on a control level.

Based on the problem description in chapter 1 we hypothesized in section 2.1 that it would be crucial to ensure a stable flow of instrument trays through the sterilization cycle. In section 3.2 we saw this supposition strengthened given that the availability of sterile instrument trays is directly reliant on a fast and efficient handling of used instrument trays. In order to ensure stable flow we deemed the Lean methodology best suited to use as a platform strategy for logistical control. Section 4.1.1 therefore provides a brief introduction into the origins of the Lean methodology. In section 4.1.2 we follow up by providing an overview of how supply chain control should be organized from a theoretical perspective. Because the translation of Lean supply chain control to the clinical practice is hard to achieve solely on a theoretical basis, this was done empirically. We therefore chose to do this in a separate follow up section, being section 4.2.

4.1.1. The Lean methodology

Lean finds its origins in the post-war Japan of the early 1950s. During this decade the island nation was recovering from the heavy industrial losses that were sustained during the Second World War [26]. As a result of rapidly accelerating economic growth local car manufacturers saw rapid increases in demand of a large variety of automobile transport modalities, varying from small cars to large transport trucks. As a result of traditional production pushed methods, this rapid increase in variable demand meant that car manufacturers had to tie up a significant amount of financial resources in maintaining large and diverse stores of supplies [26], [27]. Here one can think of large batches of car parts and semi-manufactured goods. In answer to this issue the Toyota car manufacturing company strived towards a paradigm shift by developing the Just-In-Time methodology. In contrast to traditional production methods, Just-in-time is flow oriented approach in which customer demand generates a product pull instead of operating by a production planning based push. Consequently, this allowed Toyota to reduce batch sizes, shorten production times and ultimately reduce the amount of inventory.

Lean revisits these principles with the addition that it strives to enhance the added value of the production steps from a customer perspective [19], [28]. It does so by continuously detecting and eliminating activities which are considered wasteful with respect to the delivered quality of a service or a product. Within the Lean framework, value stream mapping (VSM) is a method which has been developed to aid the implementation of the Lean philosophy in organizational structures [19], [29]. The method offers a visual representation of the process flow so that it becomes easier to identify redundant process steps. In VSM it is customary to place all the work processes and physical goods flows in a horizontal orientation to distinguish them from vertically orientated information flows [29]. VSM also requires us to establish flow related KPI measures to monitor if the proposed enhancements bear fruit in practice.

When placing Lean in the context of the instrument sterilization cycle, the method can be used to reduce production bound inventory. Reduced flow time in the instrument sterilization cycle, for example, leads to less instruments being tied up in the process chain [28]. This especially holds true for situations where deliberate flow interruptions, for example during batched production, are removed [30]. Another potential for inventory reduction can be found in accurately reducing the variety of instruments used for a procedure by standardizing the surgery order protocols. According to the Lean philosophy this can be achieved by gearing the surgery order protocols towards customer based demand instead of care provider based preference [31].

4.1.2. Defining and using performance indicators in a supply chain control framework

In section 4.1.1 we discovered that Lean can be used to optimize supply chains, like the instrument sterilization cycle, by examining the work process from the perspective of added value. To determine if the proposed changes bear fruit in practice it is common practice to formulate performance indicators by which systemic changes can be measured over time. Let us now try to employ this knowledge within the context of supply chain control.

As explained in the introduction of this chapter, we would like to determine how the current instrument sterilization cycle is controlled compared to a theoretical golden standard in supply chain management. According to literature, supply chain control can be defined according to the following four criteria:

- 1) Supply chains must be geared to deliver the best quality possible within the constraints of the available resources [32], [33].
- 2) Supply chains should be responsive to the customer need [32], [33]. This means that orders should be tuned to the desires of the customer and these desires should be met in a timely fashion.
- 3) Supply chains should ensure robust work flow [32]–[34]. To achieve robustness, work processes must be kept simple, error resistant and aligned over multiple departments to minimize production bound inventory.
- 4) Supply chains should allow for flexibility to deal with continuously shifting demands [32]–[34].

These principles are met by employing a regulation mechanism which closely resembles the Demming Plan-Do-Check-Act (PDCA) cycle (figure 3) [18], [35]. In short, the operational goals and performance parameters should be defined in a logistical policy which is consistently enforced over the entire supply chain [18]. These goals and parameters serve as an input for the production planning which governs the future execution of the supply chain processes. During the execution of the work processes all sub-departments and employees make their individual decisions on how to fulfil or deviate from the planned production. After execution of the work processes the output of the processes is compared to the original planning to detect deviations from the goals based on the performance parameters which were framed in the production planning. If deviations occur, either the production planning or the execution of the work processes can be adjusted.

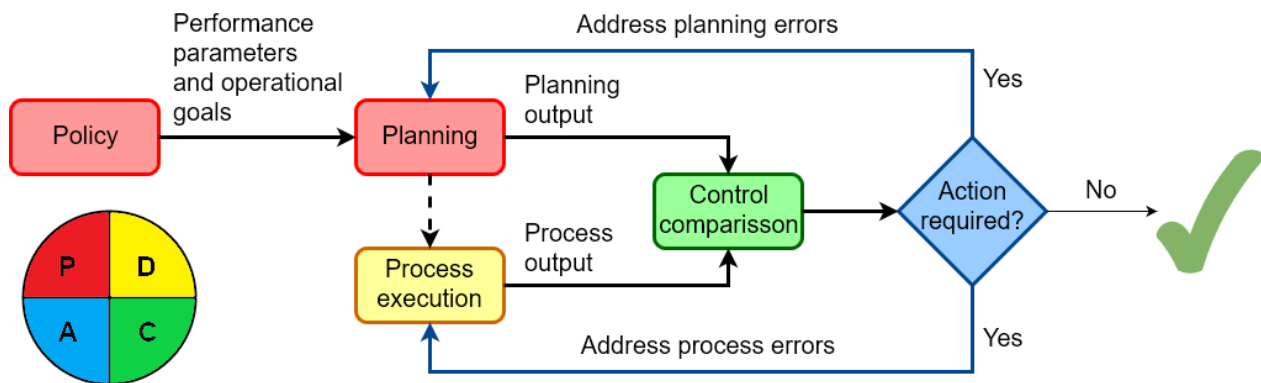


Figure 3. A schematic representation of the theoretical control mechanism for supply chains [18]. In the bottom left corner the Demming PDCA cycle is depicted [35]. The colors in the control mechanism depict which steps of the PDCA cycle are resembled.

Unfortunately we found ourselves unable to expand these criteria to workable performance indicators based on fully theoretical fundament. We therefore chose to translate the obtained knowledge in this section to a sterilization cycle control policy by combining theoretical knowledge with empirically obtained information in section 4.2. The most important aim of doing so is to formulate the KPIs required to enforce the Lean methodology over the sterilization cycle.

4.2. Translating Lean into logistical policy

In the theoretical section (4.1) we discovered that supply chain control is defined by four key criteria. Supply chains must (1) deliver quality, (2) be responsive to customer need, (3) ensure a robust workflow and (4) allow for flexibility. These criteria, however, are not operationalized to be used in a clinical setting. In order to achieve operationalized control criteria for a clinical setting, we utilized the stakeholder interviews with SD management, two OAs and a clinical physicist to split these for control criteria into 9 sub criteria which are applicable to all the aspects of the instrument sterilization cycle (figure 4). The exact definitions of these sub-criteria can be found in supplement 3.

By discussing the four criteria for supply chain control with the stakeholders we came to the following rationale.

1. The delivered quality was considered to be the most important operational criterion which can be broken down into two components: instrument safety and adequate instrument tray composition relative to the procedures for which the tray is used. The definition of instrument safety, however, varies as instrument trays flow through the sterilization cycle. Here the functional safety of the instruments should be guaranteed continuously throughout the chain whilst sterility is a variable parameter depending on instrument usage. The final sub-division of quality should therefore be defined by instrument sterility (i), instrument safety/functionality (ii), and instrument tray composition (iii).
2. The responsiveness of the sterilization cycle, on the other hand, can be broken down into two sub-components. This was done because parallel process flows, like generating a surgery planning, heavily rely on the continuous availability of instruments. It is therefore crucial to know where instruments reside in the sterilization cycle (v) and to know how fast they can be processed in order to be used again (iv).
3. From an employee point of view it is important to have a robust and workable process chain. This process robustness can be broken down to the perceived complexity of the work processes (vi) and the physical workload (vii) on the one hand, and the extent to which supply levels can be accurately managed without shortages on the other (viii). These three sub-components were included into the final criteria as well.
4. The last criterion, flexibility did not require any emphasis from a clinical perspective. Therefore it was included as a single criterion (ix).

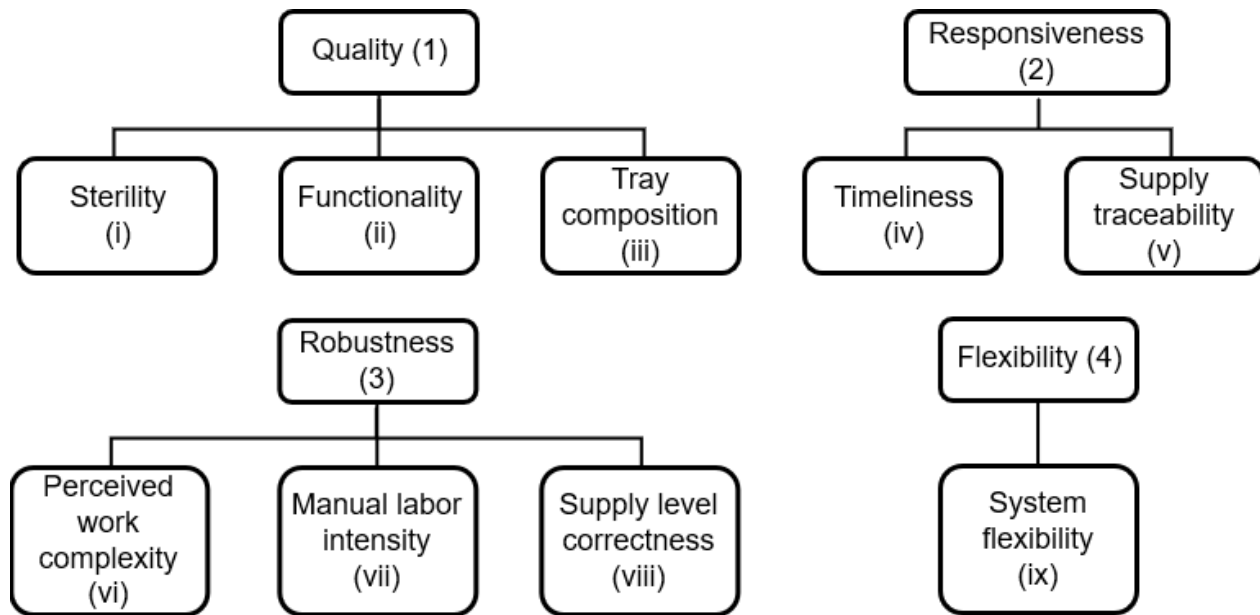


Figure 4. The subdivision of the four control criteria into their 9 clinically relevant sub-criteria.

These 9 criteria, however, were generated to cover the viewpoints of multiple stakeholders such as OAs, CSSD employees, department managers, surgeons and patients. In 1992, Lee and Billington postulated that the performance measurement of a supply chain should always be dictated by the customer stakeholder to which the supply chain serves [36]. This is in accordance with the Lean philosophy explained in 4.1.1, which states that the quality of a delivered service or product should be defined by the customer. In context of the instrument sterilization cycle the ultimate customer stakeholder would be the patient. Because patients are nescient to the clinical factors that are at play in the instrument sterilization cycle, however, we therefore have to assume that all medical staff serves the patient's interests without pursuing their personal agendas.

In 2000 Campbell et al. tried to determine which aspects of care, patients use most to define healthcare quality [37]. In their work they stated that patients generally attach more value to patient centeredness, amenities and the technical performance of care and that they are less interested in care efficiency and cost-effectiveness [37], [38]. From this perspective we assumed that out of the 9 operational criteria **instrument sterility, instrument safety/functionality, tray composition and timeliness** are the most important quality criteria to reflect the patients interests. Therefore these four criteria should be used as customer centered evaluation criteria for the work processes of the instrument supply chain.

Now the question remains of how to define our KPIs in relation to these four customer centered criteria. Important KPI examples from both Lean and supply chain management perspectives are the process lead time, the order fill rates and the first time quality [29], [33], [36]. Here the lead time (LT) can be defined as the amount of time between the initial order of a product and the moment of delivery [29]. When applying this definition to a single work process the LT essentially boils down to the sum of the wait time towards the start of the process (WT) and the time it takes to complete the specific work process (PT) (figure 5). The order fill rate (FR%) on the other hand is defined as the percentage to which an order is completed at the moment of delivery [36]. This means that if four out of five of the ordered instruments are delivered the FR% equals 80%. As such the LTs and FR% can be used as adequate measures to quantify process timeliness.

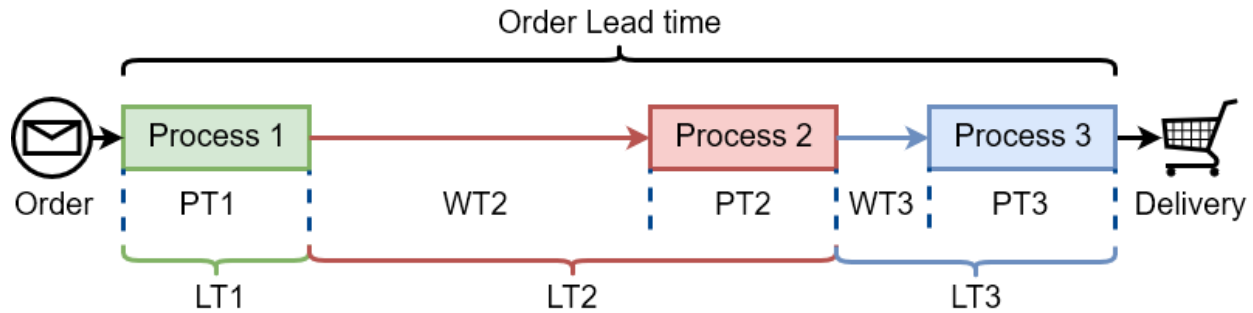


Figure 5. Schematic representation of the definitions Lead time (LT), Process time (PT) and Wait time (WT).

Last, there is the first time quality which is a frequency measure for how often a process step is conducted in a correct fashion at the first attempt. As demonstrated before, the concept of quality can be divided into three clinically relevant sub-components. Because of the inherent complexity of the concept of quality, it is impossible to define a single quality measure that can be applied to all processes. We would therefore have to specify workable definitions of the first time quality on a single processes basis. This was done as follows. Under the assumption that work process are generally conducted in a correct fashion we first of all chose to use a more convenient measure for first time quality, being first time error rates (ER). In analogy to the definition of first quality, the ER is a frequency measure for how often a process step is conducted incorrectly at the first attempt. In the next step we defined the most likely errors per work process, which can be summarized as done in table 3.

Table 3. The most likely first time errors (ER) per work process

Process	Possible errors	Notation
Surgery	Wrong tray composition Missing instruments after surgery Failure to address lacking instrument functionality	ER _{TC} ER _{MIS} ER _F
Tray check & contents management	Wrong tray composition Failure to address lacking instrument functionality	ER _{TC} ER _F
Transport to and from CSSD	-	
CSSD process	Wrong tray composition Lacking instrument sterility	ER _{TC} ER _S
Surgery procedure cart preparation	Wrong order protocol composition Lacking instrument sterility	ER _{OC} ER _S

4.3. Evaluating the system using the Key Performance Indicators

Now that we have gained an understanding of supply chain control and know which KPIs are suitable to arrange supply chain control from a Lean perspective, we can investigate how control is organized in practice. After having interviewed the stakeholders involved in the sterilization cycle we have found that to the best of our knowledge, none of the performance indicators formulated in section 4.1.2 are monitored by the IT support systems used at the OLVG. Moreover, sterilization of the instrument trays is conducted as a mostly non-planned process in which sterilization takes place according to an “as soon as possible” principle. Following this principle an informal distinction is made between standard priority instrument trays, high priority trays and rush orders. According to Clinium policy standards, priority trays are processed at the Clinium CSSD facility within 24 hours after reception whereas high priority trays

should be returned the same day. Rush orders on the other hand are processed instantly and can be returned in three hours excluding transport time.

Because no performance measures are known to us we tried to estimate the system's performance based on ethnographic observations (table 4). To determine the overall LT of the reusable instrument supply chain we assumed that the chain starts by acquiring soiled instruments after the surgery is conducted, and ends when clean and sterile instruments are delivered at the start of surgery. The PTs and WT for the CSSD process chain was based on Clinium's company policy explained above. Note that none of the first time error rates (ER) could be determined from the observations, nor from stakeholder interviews.

Table 4. Estimates of the lead times (LT), process times (PT), wait times (WT), Fill Rates (FR%) and the first time error rates (ER) for the internal process steps of the sterilization cycle.

Process	Time related parameters	Error rates
Surgery	LT = Not taken into account for sterilization cycle	ER _{TC} = - (**) ER _{MIS} = - (**) ER _F = - (**)
Tray check & contents management	LT = 5 to 20 minutes per surgery	ER _{TC} = - (*) ER _F = - (**)
Transport to and from CSSD	LT (min/max/average) = 1.5/11.5/4.8 hours (Deliveries at 6am, noon, 2pm, 3:30pm and 6:30 pm)	
CSSD process	WT (rush order) = 0 hour max policy WT (high priority) = 9 hour max policy WT (normal) = 21 hour max policy PT = 3 hours FR% ≥ 99% (policy)	ER _{TC} = - (**) ER _S = - (*)
Surgery procedure cart preparation	LT= 5 to 20 minutes per cart FR% (Initial process) = ? (no policy; (#)) FR% (surgery start) = 100% (policy; (##))	ER _{OC} = - (**) ER _S = - (**)
Full sterilization cycle	LT (rush order/high priority/normal/max) = 6/15/34/41 hours	

(*) Employees not able to estimate ER. Data not **disclosed** by the department/ company

(**) Employees not able to estimate ER. Data not **recorded** by the department/ company

(#) If instrument is absent a rush order is placed

(##) If instrument is absent an alternative instrument will have to be provided from SD main storage

4.4. Alternative performance quantification

In section 4.3 we determined that none of the formulated performance indicators are monitored by the supporting IT systems. Now let us investigate if the data that IS recorded by these systems can be utilized to derive other performance measures. When looking at figure 2 in section 3.2.2 it can be observed that a data evaluation can be performed on data obtained from six sources; the EPF and ERP systems of OLVG East and the T&T systems used at on the OR, the IRD and the CSSDs of Clinium and CSA West. In the same section we concluded that the ERP system of OLVG East is only used to document the financial transaction related to the sterilization cycle. While this could provide insight into the amount of newly purchased instruments it does not give any information on how the sterilization cycle performs. The data from this system will therefore not be taken into account for the data evaluation. Furthermore we discovered that the IRD tracing system is only used to document a small fraction of the repairs conducted by the IRD. We

therefore hypothesize that the added value of this information will be limited, for which reason the data of this system will not be taken into account as well.

The data of the CSSD T&T system we can only use in part. Next to location tracing, the CSSD T&T system documents quality related performance measures in terms of sterility and tray composition. For the quality data we assumed, however, that it cannot be utilized for a further investigation. This assumption was made based on the fact that the remaining systems do not monitor instrument tray sterility or tray composition. This makes it hard to determine how tray sterility and composition change as the instrument trays flow through the sterilization cycle. Furthermore, assuming that sterile trays are treated carefully, tray sterility is only actively influenced during the sterilization process. Therefore the sterility quality measure should only be regarded as an important output measure for this specific process.

The data from the remaining systems can only give us an idea of the throughput of the sterilization cycle which is measured at three points (figure 6). Here the EPF-system documents the requests for instruments per procedure type while the OR tracing system is used to document the usage of all instrument trays per procedure type. Comparing these two head to head should enable us to determine the extent to which the ordered instruments per surgery order protocol are actually used in practice. Furthermore, the CSSD T&T system registers the amount of sterilizations for all used instrument trays and should therefore reflect the usage that is documented in the OR tracing system.

If a throughput analysis were to be carried out over all specialisms at OLVG, the investigation would involve a vast amount of data. For this reason the scope was narrowed down by looking at the instrument tray data of a single surgical specialist department, the Urology department. As explained in section 1.2, the Urology department performed surgery on both hospital locations until March 1st 2017. In practice this means that instrument sterilization for this department was arranged over two separate sterilization cycles, one involving Clinium CSSD and one involving CSA West. To analyze the throughput of the sterilization cycle for Urology, we therefore chose to utilize the following datasets over a time period ranging from March 1st 2017 until May 31st 2017:

- 1) From the Business Services department, data was requested from the EPF system regarding;
 - a) The amount and specification of the procedures conducted per surgery for the urology department of OLVG East.
 - b) The amount and specification of the instrument trays requested per surgery for the Urology department of OLVG East.
- 2) From the SD of OLVG East, data was requested from the OR tracing system regarding;
 - a) The amount and specification of the instrument trays which were utilized for the urology surgeries.
 - b) The surgery order protocols for a selection of the 10 most frequent Urology procedures.
- 3) From the CSSD of OLVG East, data was requested from the CSSD T&T system regarding;
 - a) The amount and specification of the instrument trays which were sterilized for the urology department.
 - b) The amount of active instrument trays for the urology department, detailing their respective contents.

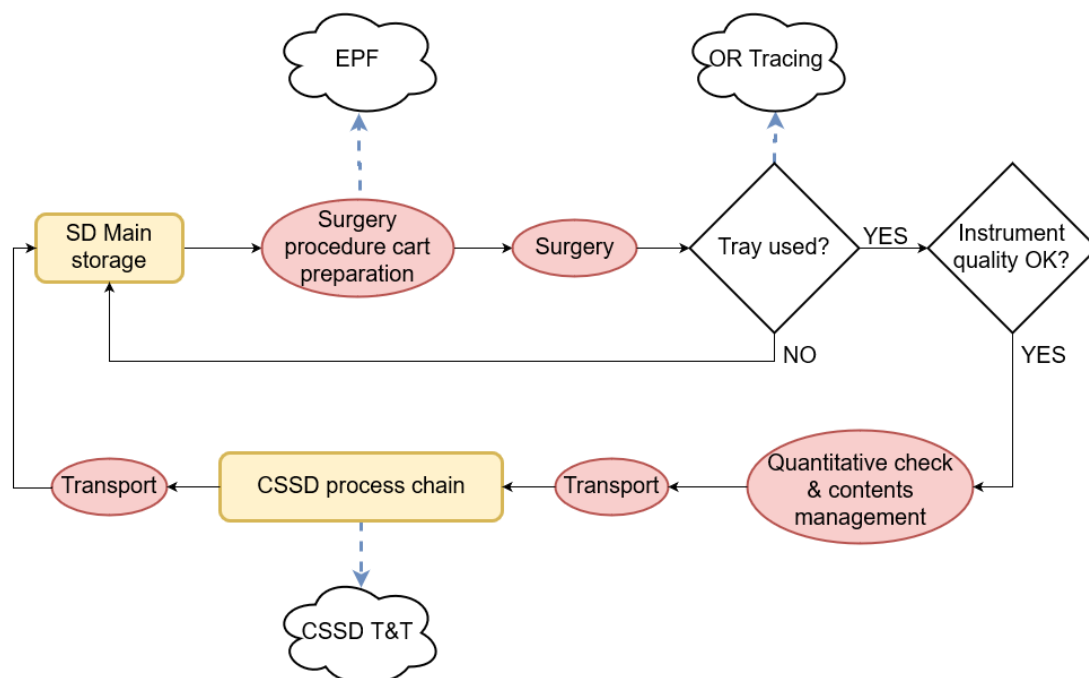


Figure 6. A simplified version of figure 2 (section 3.2.2). Here we can see that the throughput of the instrument sterilization cycle can be measured at the EPF, the OR Tracing and CSSD T&T systems.

Over the three remaining datasets an average throughput of 1173 instruments was recorded over 333 instrument entries. In order to facilitate a throughput comparison between the datasets we first had to find out how many of these 333 entries concern unique instrument tray types. After establishing the amount of unique instrument tray types we can then sum the throughput per instrument tray type and per dataset. In short the data manipulation looked as follows.

As a first step we removed the data that corresponded to disposable instruments (120 entries, predominantly in OR Tracing dataset). In a subsequent step we deleted all data doubles (86 entries) which were present over the three datasets. As a result we found that the manipulated data included 127 unique data entry types corresponding to 127 different tray types. As stated before the recorded throughput was counted per dataset over these 127 unique tray types. Overall we found that only 17 tray types showed a recorded throughput of higher than 0 for all three datasets. An example of the retrieved throughput data can be found in table 5.

Table 5. An example of the throughput data that was retrieved from the three previously selected IT monitoring systems used at OLVG.

Tray name	Tray throughput in EPF	Tray throughput in OR Tracing system	Tray throughput in CSSD T&T
OLVG Klein urologisch setje VOORRANGSNET	17 ("MIDDLE")	15 ("LOW")	23 ("HIGH")
OLVG Lampendop OK ALG VOORRANG	9 ("HIGH")	0 ("LOW")	0 ("LOW")
OLVG LAP TANGEN UROLOGIE	7 ("HIGH")	0 ("LOW")	0 ("LOW")
OLVG Lap tangen urologie VOORRANGSSET	0 ("LOW")	10 ("MIDDLE")	13 ("HIGH")
OLVG Laparoscop 0° 10 mm	8 ("HIGH")	1 ("MIDDLE")	0 ("LOW")

Now that we have summed the throughput data per instrument tray type we can data patterns between the three datasets. When we look at the simplified flowchart in figure 6 we would expect to see a certain pattern in the throughput data over these three systems. Here our expectation is that instrument flow through sterilization cycle can be described as a lossless system. This means that if we order 10 trays according to the EPF, we expect that the OR Tracing system documents an instrument usage of 10 which in turn leads to the sterilization of 10 trays at the CSSD. Since we cannot quantify the return of unused trays during surgery, what might happen is that the throughput recorded at the OR Tracing system is lower than what was originally ordered at the EPF. In this case one would for instance record 10 ordered trays at the EPF, whilst the throughput documented at both the OR Tracing and CSSD T&T equals 8 trays. In any case we can observe that the throughputs documented at the OR Tracing and CSSD T&T should be equal.

For a substantial amount of instrument trays, however, this was not found to be the case. Moreover, if we look at the example given in table 5 we can see that only two out of the five tray types adhere to this expected pattern (**OLVG Lampendop** and **OLVG LAP TANGEN**). To investigate to what extent the measured throughput data deviates from these expected patterns we continued our investigation by labelling the throughputs for the respective throughput systems (Figure 7 and **Comparison of datasets.xlsx; sheet “Sum of trays”**). In short this labeling was done by comparing the throughputs for a given instrument tray over the three respective monitoring systems. The throughput counts per monitoring systems were subsequently classified as “HIGH”, “MIDDLE” or “LOW” according to the following analogy:

- If the measured throughput of a specific instrument tray was found to be high in one dataset compared to other datasets it was registered as “HIGH”
- If the measured throughput of a specific instrument tray was found to be between the measured throughputs of two other datasets it was classified as “MIDDLE”
- And if the reported throughput was the lowest it was labeled “LOW”
- In some cases the instrument tray counts were equal over two or more datasets, this was documented and classified as “HIGH”, “MIDDLE” or “LOW” as well.

To give an example of what this looks like in practice, the classification of the datasets per instrument tray type is also demonstrated in table 5. For the final overview of the data comparison as demonstrated in figure 7, we summed the classifications “HIGH”, “MIDDLE” or “LOW” over the three datasets. Going from the analogy that we explained before based on figure 6, what we expect to see is that the throughput counts should be either equal over all datasets or should be “HIGH” for the “EPF” and “LOW” for “OR Tracing = CSSD T&T”

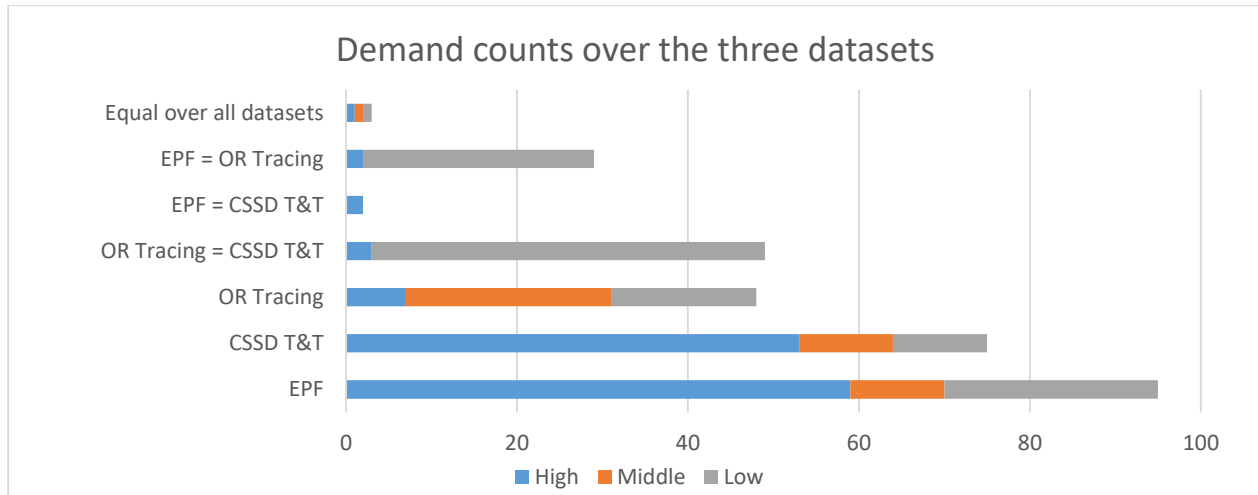


Figure 7. A visual representation of the summed classifications for all the three datasets. As explained in this section throughput counts for the three IT systems were classified as “HIGH”, “MIDDLE” or “LOW” per given instrument tray type. Where instrument tray usage equaled between the OR tracing dataset and the CSSD T&T dataset, the data is displayed under “OR tracing = CSSD T&T”. Similarly we also display data for “EPF=CSSD T&T”, “EPF=OR tracing” and “Equal over all three datasets”.

What can be clearly observed is that the expected patterns in the summed classifications in figure 7 are scarcely found in practice. Next to the EPF data set, especially the CSSD T&T dataset is frequently classified as “HIGH”. This of course is rather unusual given that this means that some tray types are more frequently sterilized than they are ordered according to the EPF dataset. To investigate this a little closer, the most significant anomalies are displayed in table 6.

Table 6. A selection of the instrument trays for which the throughput count for the CSSD T&T was classified as “HIGH”. Note that for the instrument trays containing “OLVG Bi-polair Tur” we also included OLVG Bi-polair Tur set + optiek 12° A22001A **07J**. This was done to give a complete overview of all available types of “OLVG Bi-polair Tur” (see text for explanation).

Row Labels	Tray requests in EPF	Count OR Tracing	Count CSSD T&T
OLVG Bi-polair Tur set + optiek 12° A22001A 07J	102 (“HIGH”)	20 (“LOW”)	25 (“MIDDLE”)
OLVG Bi-polair Tur set + optiek 12° A22001A 11E	0 (“LOW”)	55 (“MIDDLE”)	59 (“HIGH”)
OLVG Bi-polair Tur set + optiek 12° A22001A H60	6 (“LOW”)	25 (“MIDDLE”)	29 (“HIGH”)
OLVG RVS maatbeker 1 liter	0 (“LOW”)	8 (“MIDDLE”)	27 (“HIGH”)
OLVG Tur net CH. 26 JT VOORRANGSSET	0 (“LOW”)	7 (“MIDDLE”)	18 (“HIGH”)
OLVG Urologisch basisnet	0 (“LOW”)	12 (“MIDDLE”)	18 (“HIGH”)
OLVG Tur net CH 24 JT VOORRANGSSET	0 (“LOW”)	9 (“MIDDLE”)	16 (“HIGH”)

In table 6 we can see the instrument tray types where the sterilization frequency is more than 15 counts higher than what could be expected from the tray requests. The fact that all trays are scanned in the OR tracing system means that these trays have indeed been used, though the OR tracing and CSSD T&T counts do not equal over the counts displayed here. In this table, special attention should be given to the **“Bi-polar Tur set”** counts. According to EPF, 108 requests have been made for these sets, 102 of which for the **type 07J**. When looking at the counts in the OR tracing and CSSD T&T datasets it can be observed that in reality the demand for **“Bi-polar Tur sets”** is balanced over the three types, **07J, 11E and H60**. When this situation was discussed with the instrument logistics employees it turned out that these sets can be used interchangeably and that of all three types are kept on supply in roughly equal amounts. It might be that this explains some of the large surpluses for the CSSD T&T counts but this has to be investigated more closely.

Another remarkable result which can be noticed in figure 7 is that the counts in the datasets rarely equal over all three datasets. This is actually what one would hope to see because it means that the order protocols are fully optimized so that all requested trays are used and eventually sterilized. If a combination of two datasets resulted in equal counts it was found that this most likely occurs for the OR tracing and CSSD T&T datasets. This is to be expected because if the utilization of trays is documented in the OR tracing system this should be reflected by the sterilization documentation. For the times that the OR tracing and CSSD T&T counts were equal, the counts mostly indicated zero usage of the respective instrument tray type.

Lastly it can be seen that the OR tracing dataset is frequently represented in the middle and low ends of the count spectrum. This can either indicate that the requested instruments on the surgery order protocols are rarely used all together or that the registration of the reusable instruments might be error prone. We can zoom in on this issue by looking at the 17 tray types where (non-zero) throughput was documented for all three datasets (figure 8). Because the amount of tray registrations in the OR tracing system are substantially lower than in the other tracing systems this figure provides a clear indication that registration errors in the OR occur on a frequent basis. This evidence is supported by an observation of internal documentation that the registration of used disposables in the OR is relatively error sensitive as well. From non-disclosed data we were able to calculate that out of the 70 surgeries conducted for the urology department in May 2017, scanning errors were documented for 30% of the surgeries. During these surgeries approximately 50% of the used disposables remained unregistered with a maximum financial value of up to 1075 euros per item.

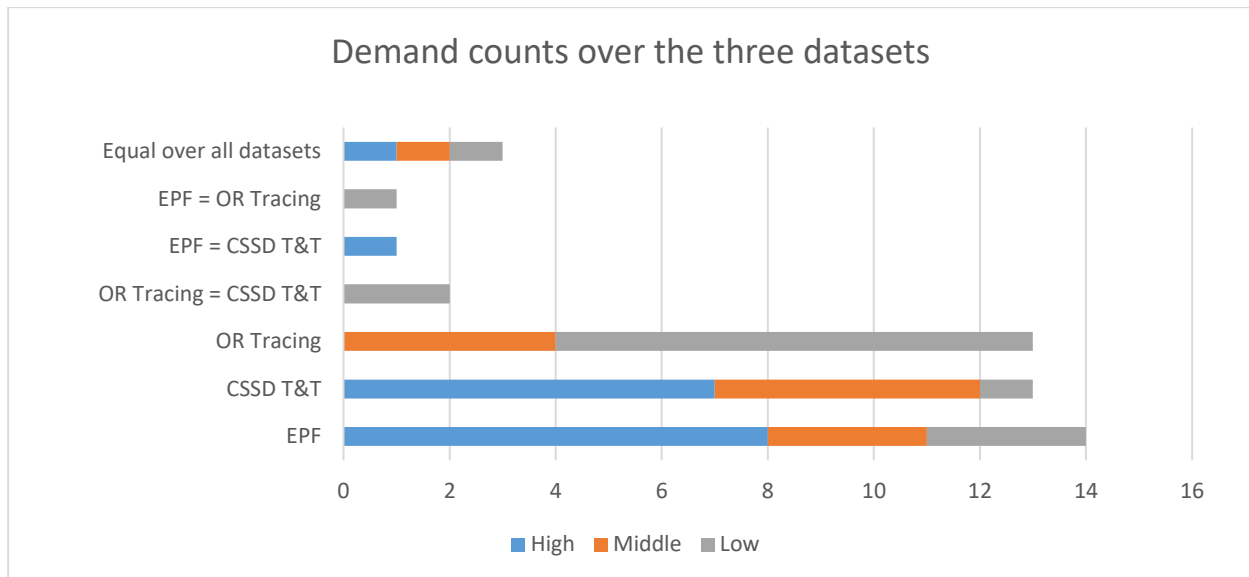


Figure 7. The throughput counts for 17 different instrument trays over the three datasets. This figure was generated in analogy to figure 6.

To summarize section 4.4, we can say that three IT support systems that are used in the instrument sterilization cycle can be utilized to quantify instrument tray throughput. Other performance measures are not measured consistently enough throughout the sterilization cycle to be utilized for performance quantification. This is mainly due to the fact that the coverage of the IT systems is limited to support the tasks of single department. Another consequence of this fragmentation is that it inhibits the OLVG's ability to obtain an unambiguous image of the overall throughput in the sterilization cycle. The raw data that was retrieved from the three IT systems contained a lot of data pollution in terms of data doubles, data regarding disposable instruments and coherent notation. After cleaning up the data we found that there were significant differences in the recorded throughput. Especially the data quality of the OR tracing system seems to be at risk due to inadequate utilization of the system in the OR. Lastly, we found out that the data from the EPF system only specifies the instruments that have been requested prior to surgery and does not include emergency requests or the amount of returned unused instruments.

4.5. Discussion

Over the course of this chapter we have investigated how supply chain control should be organized from a theoretical perspective. As explained in section 4.1 we hypothesized in chapter 2 that it would be crucial to ensure a stable flow of instrument trays through the sterilization cycle. In order to do so we deemed the Lean methodology best suited to use as a platform strategy to ensure logistical control. In sections 4.1 and 4.2 we therefore devised a supply chain control mechanism which was founded on this principle, and we formulated performance measures by which Lean based control can be enforced. In this section we will reflect on the sections 4.3 and 4.4 to determine to what extent the control mechanism utilized at OLVG is in accordance with this theoretical control mechanism.

When we look at the results of section 4.3, we can clearly see that none of the performance measures established in sections 4.1 and 4.2 are used to govern the instrument sterilization cycle. As a consequence, the work processes are mostly executed in a non-planned fashion. Instead instrument sterilization takes place according to an "as soon as possible" principle in which an informal distinction is made between standard priority instrument trays, high priority trays and rush orders. As the sterilization cycle is lacking

crucial parts of its planning functions, the overall control mechanism can be typified as highly reactive and primed on short term operational solutions (figure 8).

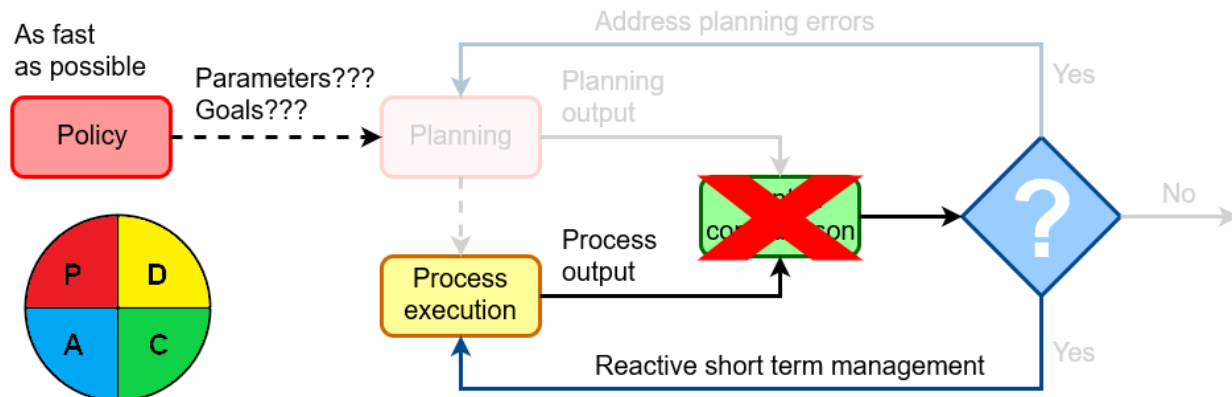


Figure 8. A representation of the strongly impaired supply chain control mechanism relative to the theoretical ideal depicted in section 4.1.2, figure 3.

To remedy this we advocate for implementing a strongly centralized planning function which should be in congruence with the organizational lay-out of the sterilization cycle. To explain why this is necessary, we will have to venture deeper into the theory involving supply chain management. At present the OLVG sterilization cycle is organized in such a way that the demand for sterile trays only influences upstream production processes to a limited extent (figure 2). The point at which this influence becomes negligible is called the customer order decoupling point (CODP) otherwise known as the production push/pull point [39]. When looking at figure 2 we can see that CODP in the sterilization cycle is located at the point where the procedure carts are prepared from the SD main storage. The rest of the sterilization cycle functions autonomously from the ordering process and replenishes the SD main storage according to the “ASAP principle”. Because all the processes leading up to the CODP are not affected by customer demand, the CODP can therefore be seen as a buffer point against the penetration of demand variability into the supply chain [39].

The exact location of the CODP in the supply chain is commonly used to characterize supply chain types. Here the possible types can be broadly summarized as follows:

- Make-to stock (MTS) - the decoupling point is located at the shipment stage
- Assemble-to-order (ATO) - the decoupling point is located at the final assembly stage
- Make-to-order (MTO) - the decoupling point is located at the fabrication and procurement stage
- Engineer-to-order (ETO) - the decoupling point is located at the design stage

As it is currently organized, the OLVG sterilization cycle can be characterized as a make to stock (MTS) supply chain. These types of supply chains generally show a high resilience against variable product demands because the processes upstream of the CODP are highly planable [39]. The fact that process planning for the OLVG sterilization cycle is not properly organized, creates a risk for stock outs and overstocking. A first solution step would therefore be to implement a central planning which forecasts demand based on previous demand [36]. Here, the use of past demand to forecast future demand is a relatively attractive attribute to plan the throughput of the sterilization system and determine the amount of stocks that have to be kept in supply. This is caused by the fact that a direct MRP planning based on the scheduled surgeries would be difficult because the surgery schedule is subject to continuous changes, as

explained in section 3.1.2. For this reason we propose to investigate the potential of a forecasting model in chapter 5.

In addition to the impaired planning function, we have discovered that the situation is exacerbated by the fact that the IT support systems are of limited use for measuring supply chain performance. This is caused by the highly fragmented nature of the IT systems and the limited coverage that the systems provide in terms of functional use and administrative coverage. As a result of this phenomenon, we found in section 4.3 that the OLVG does not maintain a coherent quality registration system which spans the entire sterilization cycle. Using the IT environment currently in place we were only able to quantify the tray throughput of the system but the overall quality of this data is questionable at best. We will therefore have to consider the question if the aforementioned introduction of centralized planning function has any implications for the IT environment that is currently in place. This will be done in chapter 6.

4.5.1. Specifying the scope of a proposed solution

In this sub-section we translate the earlier found problems regarding a lack of process planning and the impaired information registration into tangible and properly demarcated solutions. In order to do so, we have to consider the scope within which we want to address these issues.

Let us first look at the Hans et al. chapter of the *“Handbook of healthcare system scheduling”* [40]. According to this chapter, healthcare planning and control can be broadly divided into four main areas of expertise; medical planning, resource capacity planning, financial planning and materials planning. In turn these expertise areas can be broken down into four hierarchical levels: strategic, tactical, offline operational and online operational (table 7). Here the hierarchical levels are characterized by a varying time horizon. Strategic decisions are often made based on long time horizons and as a consequence are subject to high variability and uncertainty in the decision parameters. In contrast, online operational decisions can be described as management on a reactive basis which allows for low flexibility because the involved decision parameters are mostly fixed. The exact timespans that are utilized for these hierarchical levels, however, vary according to the processes involved.

Depending on the problem to which the planning and control framework is applied, additional areas of expertise can be added [40]. For application in the current situation it was chosen to add information management planning as an additional area of expertise as recommended in the discussion section of the Hans et al. chapter. Here the aim of information management is to collect, integrate and process adequate data to enhance offline operational and, more importantly, tactical planning functions [41]. The hierarchical decomposition of this area of expertise was founded on the knowledge hierarchy which was explained and improved by Hicks and his colleagues in 2006. In addition to this extra area of expertise, we also chose to supplement the definitions that can be found in the materials planning column. This was done based on the definitions formulated in section 2.2.2 of the van Amstel thesis [18].

Table 7. This table displays the framework for health care planning and control as adapted from the “Handbook of healthcare system scheduling”, chapter 12: “A Framework for Health Care Planning and Control”. The framework was expanded with a fifth area of management expertise according to the views of Hicks and his colleagues [40], [41]. Furthermore, the definitions in the materials planning column were supplemented based on the definitions formulated in section 2.2.2 of the van Amstel thesis [2]. In this table the columns and rows that deserve our main attention with respect to the OLVG case are marked in grey.

	Medical planning	Resource capacity planning	Financial planning	Materials planning	Information management planning
Strategic	R&D of medical protocols	Case mix planning, capacity planning Workforce planning	Investment plans, contracting insurance companies	Supply chain design Capacity dimensioning Define key quality indicators and set standards	Define and select data sources, implement adequate information systems
Tactical	Treatment protocol selection	Block planning, staffing, admission planning	Budget and cost allocation	Supplier selection Determining desired production speeds, fill rates and lead times Monitoring production progress	Information integration and processing to facilitate tactical planning functions
Operational offline	Individual diagnosis and treatment planning	Appointment and workforce scheduling	DRG billing, cash flow analysis	Purchasing process, determining order sizes Department based scheduling Monitoring production progress	Data checking, correcting erroneous data, using correct information for operational interventions if necessary
Operational online	Triage, diagnosing emergencies, complications	Monitoring emergency coordination	Billing complications and changes	Rush ordering, inventory replenishment Incident management	Adequate data collection, managing system failures and errors

What can be deduced from this framework is that planning and execution of work processes on an operational level, is inherently reliant on the correct execution of higher hierarchical planning functions. If a hospital fails to select a treatment protocol corresponding to a certain diagnosis, for example, it will become more complicated to plan the right treatment for that specific diagnosis. This interdependence, however, can also be found between the different fields of expertise. When following the same example regarding treatment protocol selection this would mean that failing to select a treatment protocol for a disease could unnecessarily complicate patient billing. If we subsequently review this framework utilizing the van Amstel thesis, we can see that the hierarchical levels can also be seen as analogous to the degree of management centralization [18]. Here, more centralized management functions are represented with higher hierarchical levels than less centralized management functions.

Let us now apply the framework to the case at hand. By claiming that we want to devise a centralized planning function we are basically saying that we want to shift managerial attention towards the higher hierarchical levels. When we focus on the **materials planning** of the sterilization cycle we can see that most of the decision factors on the **strategic level** are already determined. Here we know what the basic supply chain design looks like at present, what the capacity dimensions of the various departments are and we are able to determine and verify the key quality indicators on which quality standards can be based.

More significant managing deficiencies, however, can be found when reviewing the decision factors of the **tactical hierarchical level**. Here the production speeds and fill rates are only defined for the processes of the central sterilization services department (CSSD) but remain to be determined over the other process in the sterilization cycle. More importantly we have observed in this chapter that the monitoring of tray

sterilization progress is problematic. The restoration of the supply chain control mechanism can therefore be typified as a tactical measure to enhance the supply chain. Since this problem initially concerns the management of tray supplies and order protocols, we will have to generate a forecasting model that is specific for instrument tray demand. Consequentially we decide that the generation of a planning for single or spare instruments falls outside of the scope for this investigation.

If we then shift our attention to the *information management planning*, we can see that a comprehensive information management strategy for the instrument sterilization cycle is lacking. This can be concluded based on the fact that the current IT environment is highly fragmented in which specific systems are used for single department purposes. With the introduction of a centralized planning, however, the aim of the information management systems shift towards providing support for the execution of work processes throughout the entire sterilization cycle. As a consequence, the development of an information management strategy will be dependent on the redesign of the supply chain control mechanism. This means that we will have to look at which input parameters we want to use for our forecasting model in order to formulate an information management strategy. Since the main focal point of our solution process will involve the creation of a planning function for the management of tray supplies and order protocols, the IT systems have to be organized accordingly. This means that a differentiation has to be made between monitoring instrument trays that flow through the sterilization cycle and monitoring the supplies of single or spare instruments.

4.6. Conclusion

In sections 4.1 and 4.2 we described how supply chain control should be organized from a Lean perspective and we formulated performance measures by which Lean based control should be enforced. In section 4.3, however, we found that these performance measures are not measured nor used in practice. Additionally, we found that the work processes in the sterilization cycle are conducted as a mostly non-planned process chain in which sterilization takes place according to an “as soon as possible” principle. As the sterilization cycle is lacking its crucial planning functions (figure 8), the overall control mechanism can therefore be typified as highly reactive and primed on short term operational solutions.

In section 4.5 we discovered that this can prove detrimental for proper stock maintenance. As we classified the sterilization cycle as a make to stock (MTS) supply chain we discovered that the customer order decoupling point (CODP; also known as the demand push/pull point) is located relatively far downstream in the supply chain. As a result most processes are reliant on a well-structured planning based production push rather than a customer based demand pull. To remedy this we proposed to develop a demand forecasting model in order to give an estimate of how much instrument trays would be required to cover demand. This model will strictly focus on a demand forecast for reusable instrument trays in the instrument sterilization cycle and will disregard the forecast of spare instruments.

Next to the lack of a central planning, we have discovered that the IT systems that are currently in place are of limited use for measuring supply chain performance and thus enforcing the materials planning. This is caused by the fact that the IT environment is highly fragmented because a coherent information management strategy is currently lacking. To formulate an information management strategy, however, we will first have to look at how the proposed planning takes shape. In addition we have found that especially the instrument tracing system over the OR is not used adequately by the employee stakeholders.

5. Demand prediction model

In chapter 4 we concluded that the OLVG East sterilization cycle can be characterized as a make to stock (MTS) supply chain. In these types of supply chains the customer order decoupling point (CODP; also known as the demand push/pull point) is located relatively far downstream in the supply chain. As a result most processes are reliant on a well-structured planning based production push rather than a customer based demand pull. Because we found that the production planning is severely impaired we hypothesized that we could restore the supply chain control mechanism by implementing a demand prediction model which can function as a guide for supply management and throughput quantification. In this chapter we therefore want to investigate the potential of a demand prediction model in order to answer sub-question 3. This prediction model should forecast instrument tray demand based on both previous demand and on the patient centered performance measures established in section 4.1 and 4.2.

To do so we first study the design considerations of the demand forecasting model in section 5.1. In section 5.2 we illustrate how the input data is utilized to generate the model. The exact outcomes of the model, however, are included in the supplementary material. The model is subsequently validated by comparing the model outcomes with actually measured data in section 5.3. Furthermore, we calculated the forecasting model accuracy based on the calculated forecasting errors. In section 5.4 we discuss the potential that this model has to improve the planning functions at OLVG. Because the generation of a forecasting model is based on actual demand data recorded at OLVG, we narrowed down the scope of the forecasting model to the Urology department. This choice was made in order to limit the amount of data which would be required to conduct the analyses in this chapter.

5.1. Design considerations for a demand forecasting model

In chapter 4 we proposed to develop a prediction model to improve the production push that is used to replenish the SD main storage. This model should generate a demand prediction based on both the previous demand for instrument trays and on the patient centered performance measures established in section 4.1 and 4.2. In this section we discuss the design considerations which we should take into account when developing the proposed forecasting model. Here the forecasting model will be developed as a proof of principle based on the Urology data. If the model proves to be functional it can be expanded to other expertise areas.

Demand forecasting is usually done in a sequence of steps; first one has to identify the goal of the forecast, second a time horizon has to be established, third a forecasting technique has to be selected and in the final two steps the forecast has to be conducted and monitored for accuracy [5]. Here the latter two steps are usually conducted as time progressing processes in which newly generated data is used to update the forecast in a time step or a continuous basis.

In consultation with SD management we have formulated the following two goals for our prediction model:

- 1) First of all we like to be able to give a correct estimation of the instrument tray supplies required to cover 97.5% of all possible instrument tray demand.
- 2) Second, we want to give a generalized idea of how surgery order protocol compilation should be adjusted to influence the amount of instrument tray supplies and instrument tray demands.

For the time horizon it was determined that a time period of 1 year should be utilized. This long time horizon was selected because the model will be used to determine the amount of financial assets which are tied up in the instrument supplies. We assume that these decisions can have relatively capital intensive

consequences for which reason we do not deem it feasible to review the amount of instrument tray supplies on a more frequent basis. Furthermore, we can see in literature that such timeframes are relatively common in a healthcare context [42]. Along with the time horizon we also selected a time resolution for demand forecasting. Here the time resolution was set to 1 week because instrument trays reside in the sterilization cycle for longer than a day on average (section 4.3).

The selection of a forecasting method and the execution of the forecast, however, require a bit more elaborate consideration. Because we want to use a forecasting model that best represents the recorded data, we first investigate how to implement the forecasting model in the current practice and consequently select the appropriate data sources. This is done in section 5.1.1. In section 5.1.2 we follow up on the data selection by reflecting on the possible forecasting methods which can be used to forecast instrument tray demand.

5.1.1. Implementing a forecast method in the current situation

Let us first focus on how we propose to implement a demand forecasting model into the current situation. In section 3.2.2 we established the ground form of the current sterilization cycle. If we disregard all the current IT systems as well as the spare instrument cycle as shown in figure 2, we can generate a flowchart as depicted in figure 9. According to this adjusted ground form we propose to establish an at this point undefined IT system which measures the throughput of the sterilization cycle. This throughput is measured directly after the surgery because this activity can be viewed as the source activity from which soiled instrument trays originate. We hypothesize that this will result in two distinct advantages that boost the attained measurement accuracy. First of all we believe that throughput measurements in this part of the system will result in a more appropriate time correlation because the substantial LTs of the follow-up processes do not have to be taken into account. This becomes especially relevant if a surgery is conducted outside of office hours so that the sterilization cycle is not able to process the trays on the same day as the day of usage. Second of all we can see that this setup allows us to distinguish between trays that are ordered and are used, and trays that are ordered and remain unused.

The measurement of instrument tray throughput in this system should not be confused with measuring instrument tray demand. In the sterilization cycle, instrument tray demand is generated by the amount of scheduled surgeries which require a subset of instruments as specified in the surgery order protocols. As explained in chapter 1, however, we are at this point uncertain whether the surgery order protocols are up to date. We therefore propose to generate a tray demand forecast based on past procedure demand. By doing this instead of directly using past tray throughput to forecast tray demand we allow ourselves to compare the actual instrument tray usage per procedure to the compilation of the order protocols. Hence it allows us to achieve goal 2, as introduced in section 5.1:

Giving a generalized idea of how surgery order protocol compilation should be adjusted to influence the amount of instrument tray supplies and instrument tray demands.

In addition, the utilization of the amount of conducted surgeries for tray demand prediction purposes can have an added practical benefit. Here the predicted amount of surgeries is a measure that is commonly used to calculate a variety of important healthcare related parameters. Examples thereof are case-mix indices, multi-factor productivity levels, healthcare billing per DBC and (potential) turnover prognoses [5], [43]. It therefore stands to reason that when prognoses are generated for the amount of surgeries to dimension future healthcare capacities, that this can also be applied to dimension instrument tray supplies.

Last we can see in figure 9 that the undefined IT system has to keep track of the PTs, WTs, and LTs of all the process steps involved in the cycle. This information can be used to determine the average speed at which the supply chain operates. By doing so the predicted demand in trays per time unit can be matched to a required stock level in the sterilization cycle. In a more advanced setup the system can also be used to keep track of the replenishment rate and the %FR at the point of order release from the CSSD.

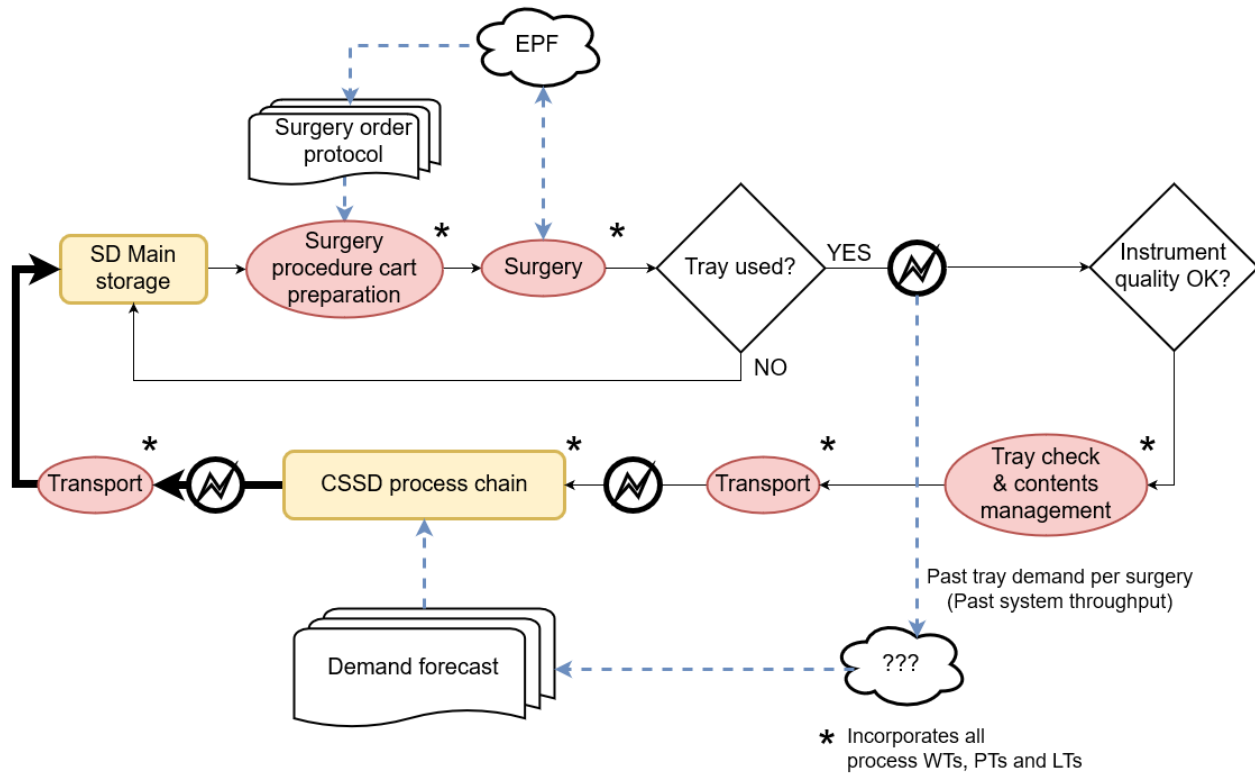


Figure 9. In this figure a flowchart of the proposed solution is depicted. The chart includes a presently undefined IT system that records past tray demand and WTs, PTs and LTs. In a more advanced setup this system can also be used to measure the replenishment rate and %FR at the far left “Transport” node where the order is pushed from the “CSSD process chain” into the “SD Main storage”.

Unfortunately the present IT environment (figure 2) does not allow for all the measurements that we propose in this section. We therefore have to determine how we can retrieve the required data to build our prediction model. Let us first look at the measurement of the LT of the instrument sterilization cycle. In section 4.3 we concluded that the current measurement systems do not record the PTs, WTs nor the LTs of the individual work processes. In the same section we therefore estimated the LT for the full sterilization cycle to be the following: six hours for rush orders, 15 hours for high priority orders, 34 hours for regular orders and 41 hours as an overall LT maximum. Because we cannot measure these values on a continuous basis we will utilize these LT estimates as fixed parameters for our prediction model.

As a data source we chose to utilize the EPF dataset, which was introduced in section 4.4, to couple the instrument tray throughput to the demand for specific surgeries. This decision was made based on the following reasoning. In section 4.4 we established that the tray throughput can be measured by three distinct measurement systems, being the EPF, OR Tracing and CSSD T&T systems. When reviewing the placement of the undefined measurement system in figure 9 we can see that the OR Tracing system as drawn in figure 2 would be the most likely candidate to use as a data source. Here this system measures

the throughput of the sterilization cycle and records the usage per procedure and per patient. The measurement quality of this system, however, was found to be lacking after a closer investigation in section 4.4 revealed that the throughput registration in the OR is most likely erroneous. When looking for an alternative data source amongst the two remaining IT systems we found that only the EPF system might provide useful information. This conclusion was reached because the CSSD T&T does not provide a coupling of the instrument tray throughput and the procedure data. The data from the EPF-system, however, does come with two limitations that have to be taken into consideration for the forecasting model. Here the EPF system documents the requests for instrument trays per procedure type regardless of the fact whether they are used during surgery or not. Furthermore, it might happen that tray requests for emergency procedures are not well documented in this system.

5.1.2. Selecting a forecasting method

In this section we investigate which forecasting methods would be appropriate to forecast future tray demand based on past procedure demand. To forecast future demand based on past demand a plethora of methods are available which strongly vary in modeling complexity. Here examples of more simplistic models are naïve forecasting and moving average models. We will demonstrate how these models function based on a numerical example (table 8).

Table 8. An example of naïve and moving average demand forecast for the “Blaas TURT” procedure.

Week	N-7	N-6	N-5	N-4	N-3	N-2	N-1	N	N+1
Recorded demand for “Blaas TURT”	10	3	5	2	6	3	2	4	2
Naïve forecast	-	10	3	5	2	6	3	2	4
3 week moving average forecast	-	-	-	6.00	3.33	4.33	3.67	3.67	3.00

As can be seen from the example, naïve forecasting models operate in a very straight forward way. This model basically assumes that demand trends and turning points cannot be predicted and therefore predicts future demand by extrapolating the past data points [44], [45]. In the example we can see that if the demand of the previous week equals 2 procedures (Table 8; week N-1), the naïve model will forecast a demand of 2 procedures for next week (Table 8; week N). In this perspective the moving average model is only slightly more advanced. In contrast to the naïve model the moving average model incorporates a more substantial demand history by averaging the demand over a specified amount of weeks [44], [45]. If the model for example incorporates a three week demand history with demand equaling 6, 3 and 2 procedures per week (Table 8; weeks N-3 to N-1), the model will forecast a demand of 3.67 procedures for week N (the sum of 6, 3 and 2 divided by 3).

When comparing the demand forecasts methods to the actual demand in the example we can see that these forecasting methods are not accurate. The reason for this inaccuracy is that the presented models do not take, or at best limitedly take, the demand variability of the example data into consideration [46]. Here demand variability can occur in two distinct forms, being non-random variability and random variability. Non-random variability usually has an assignable cause for which various correction methods can be applied on the demand forecast. Important examples of non-random variability are seasonal variability or trend variability [44], [47]. Because we are presently only interested in the question whether

or not we can predict future demand based on past demand we will only take random variability into consideration.

A relatively facile way to account for this variability is to add a stochastic component into the demand forecast [18]. This can be done by determining the probability density distribution based on the variations found in the past demand data. These empirical distributions can in turn be fitted to parametric distributions which allow for statistical extrapolation of the original data [48]. Examples of such parametric distributions are gamma, beta, normal and Poisson distributions. If we put the use of stochastic forecasting models in perspective with developments in other industries, we can see why healthcare is often regarded as a laggard industry when it comes to the implementation of innovative ideas [18], [49]. This basic idea of stochastic supply management saw its first implementation in other industries in the 1920s [18].

When we look at the literature for both supply chain management and for healthcare planning two popular examples of parametric distributions can be found which can be used for demand forecasting [5], [50], [51]. In supply chain management demand forecasts are commonly conducted by making use of the normal distribution (formula 1) [50], [51]. Here the bell curve of the normal distribution describes where the data points are likely to be located relative to the measured average (figure 9). In the given example of formula 1 we demonstrate how a variable (X) is normally distributed as a function of μ and σ^2 . Here μ represents the mean of the measured values whilst σ^2 represents the calculated variance.

Formula 1.

$$P_N(X = k) = \frac{1}{\sqrt{2\pi\sigma^2}} e^{-\frac{(k-\mu)^2}{2\sigma^2}}$$

A significant amount of probabilistic healthcare processes, on the other hand, can be described with the so called Poisson distribution (figure 9) [5]. Two commonly used examples of such processes are the probability distributions which describe patient arrival rates or patient service rates. The Poisson distribution itself can be described according to the mathematical equation of Formula 2 [52]. In this formula the k variable represents how often a specific event occurs per time unit whereas the λ constant resembles the average occurrence rate of that event.

Formula 2.

$$P_P(X = k) = \frac{\lambda^k}{k!} e^{-\lambda}$$

Generally speaking the shape of the Poisson distribution closely resembles a negative exponential for lower occurrence rates whilst shifting towards the shape of a right skewed normal distribution for higher occurrence rates [52]. It is therefore assumed that for higher average occurrence rates the data can also be modelled by using the normal distribution [50]. Here the key in knowing when to apply a Poisson or a normal distribution lies in the extent to which either of the two parametric distributions fit the observed possibility densities. In section 5.2 we therefore compare the data with both Poisson and normal parametric distributions to ascertain which distribution provides the best fit for the data.

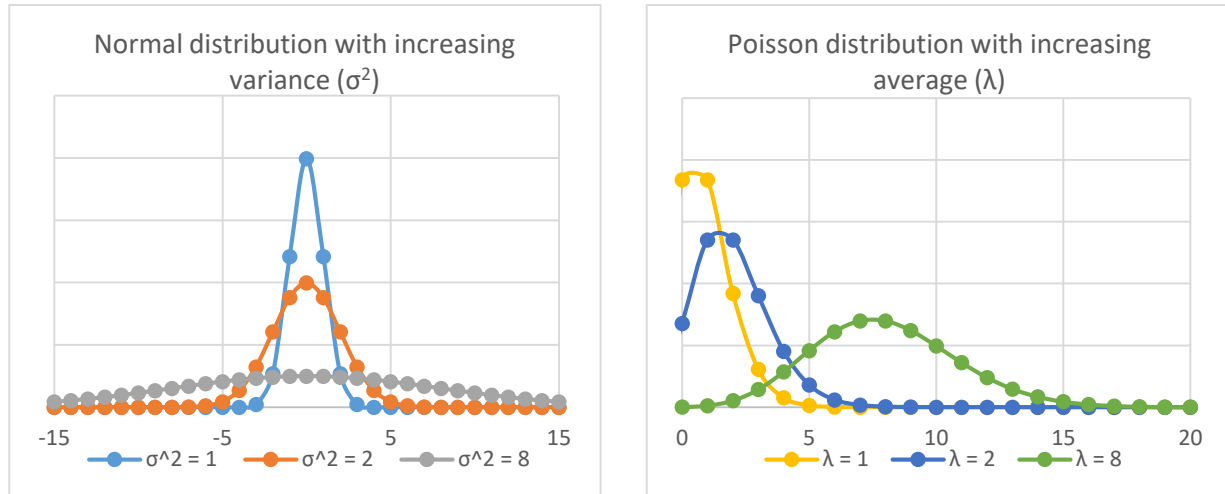


Figure 9. Examples of both the Poisson and Normal distribution

5.2. Generating a stochastic prediction model

In the previous section we explained that we want to build a tray demand forecasting model based on both past procedure demand as documented in the EPF dataset, and the Lead time (LT) performance indicator. Here the full EPF dataset summarizes all Urology surgeries conducted from January 1st 2016 until May 31st 2017 in terms of surgery date, patient ID, location, conducted procedures and requested instruments. As in section 4.4 we decided to only use the last 14 weeks of this dataset which spans the time period between March 1st 2017 and May 31st 2017. Recall that this was done for the reason that the production of the urology department was distributed over both OLVG locations prior to March 1st 2017.

In section 5.1.2 we explained that we want to make use of a stochastic forecasting method in order to account for the variability in the demand data. To do so we chose to look into the use of two possible parametric distributions, being the normal and the Poisson distribution. In this section we provide an explanation as to which parametric distribution was selected and elaborate on how the overall prediction model is built. The model building process included the following steps:

- 1) First we determined which parametric distribution provides the best fit for the EPF demand data (section 5.2.1).
- 2) Based on the data fitting we selected the most suitable distribution and used it to build a cross table which specifies the relationship between the procedures and the requested trays per procedure (section 5.2.2).
- 3) Using the cross table we calculated the average demand for instrument trays on a weekly basis (section 5.2.2).
- 4) The average demand was used to calculate the left-sided 97.5% confidence interval which should represent 97.5% of all possible demand (section 5.2.2).
- 5) The model was validated by comparing the outcomes of the model to the actual demand for single instrument trays (section 5.3). Furthermore, we calculated the forecast accuracy based on the calculated forecasting errors.

For this process it was necessary to split the aforementioned 14 week dataset into two parts; a training dataset which spans the first 10 weeks and a testing dataset which spans the last four weeks. The demand forecasting model was built based on the data of the training dataset, according to the sequence steps as

described above. The testing dataset was predominantly utilized in section 5.3 to determine the forecasting accuracy.

5.2.1. Determining the best parametric fit

In order to determine the best parametric fit let us first explore the EPF dataset. When we examine the original data of the EPF dataset, we can conclude that 1 surgery can include up to four different procedures (**Demand prediction.xlsx; sheet "Data"**). Over the entire EPF dataset we were able to distinguish 93 different procedure types which were conducted with varying frequency (**sheet "Procedure count"**). Of these 93 different procedures the first 25 accounted for 80.39% of all procedures conducted over the entire time span of 75 weeks. In SCM science this phenomenon is dubbed the Pareto-principle which states that roughly 20% of the product diversity satisfies roughly 80% of the overall demand [53], [54].

Looking at the remaining 68 procedures we can see that the frequency at which they are conducted amounts to 250 procedures over 75 weeks. This means that if all these 68 procedures were to be conducted with the same instrument tray, it would require less than four trays per week to cover the average demand. As a proof of principle, we therefore wanted to investigate whether the use of the first 25 procedures would be sufficient to generate an accurate prognosis. To do so we decided to separately sum the occurrences of the 25 procedures on a weekly basis. In this way we were able to count how often a certain procedure frequency occurs in order to calculate the weekly probability density per procedure per week (**sheet "Weekly prob.dens. procedure"**).

To determine which parametric distribution would yield the best fit to the demand data, we randomly selected four of the 25 procedures and plotted their empirically determined probability densities versus their corresponding parametric probability distribution functions (**sheet "Parametric fit"**). In addition we also plotted the empirically determined probability density summed over all 25 procedures versus its corresponding parametric probability distribution function. The results of this investigation can be observed in figure 10 and table 9. Here we found that both the Normal and Poisson distribution offer a decent fit for higher average demand levels, with R^2 values varying between 0.998 and 0.947. As the demand for a procedure decreases, however, the fit for the normal distribution decreases significantly with R^2 values dropping below 0.400, whilst no notable differences are observed for the Poisson fit (table 9). These findings are in accordance with the earlier referenced literature which stated that Poisson distributions can only be modelled by using Normal distributions for higher average demand levels [50]. It is for this reason that we choose to utilize the Poisson distribution to forecast future demand.

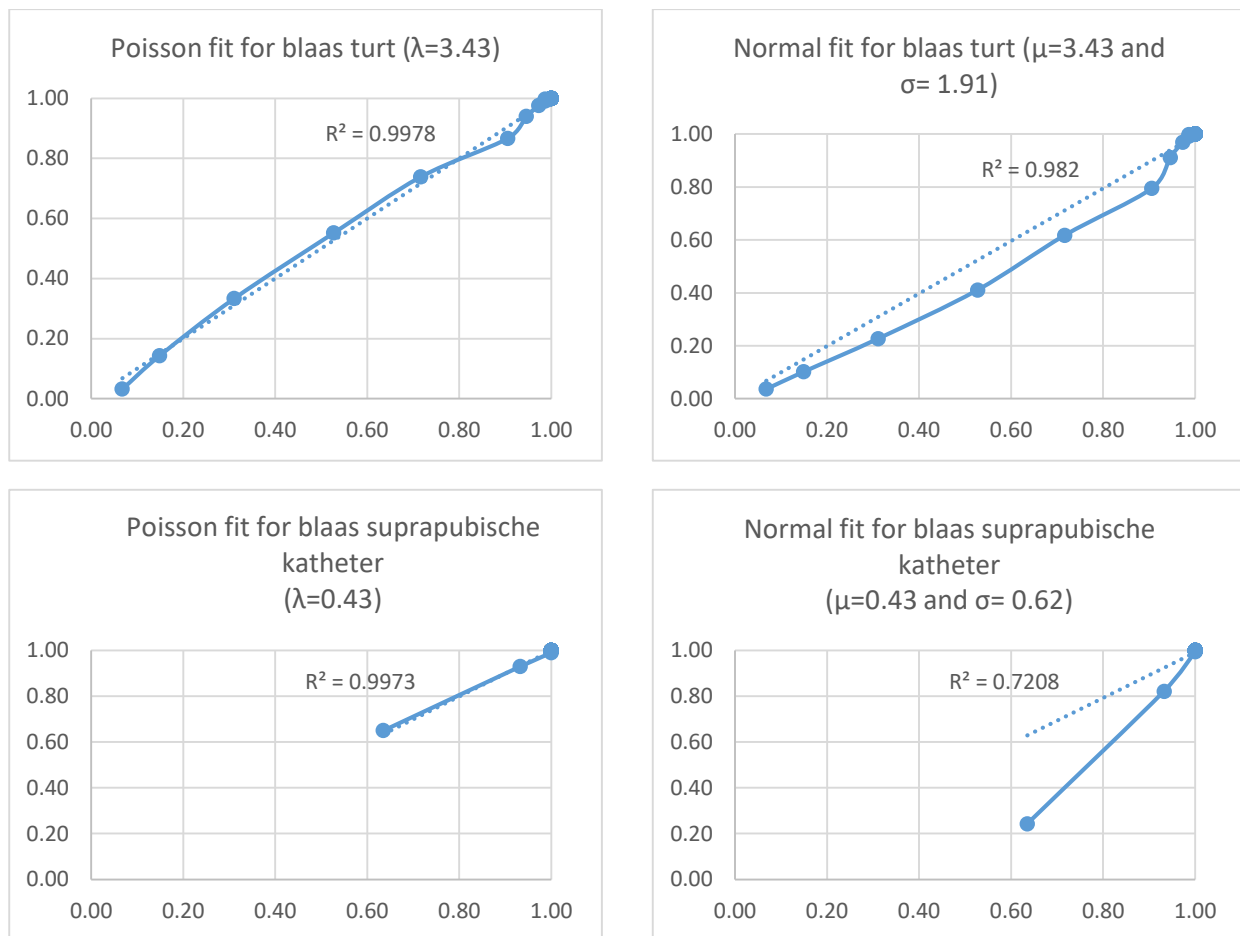


Figure 10. By comparing the fits of the empirical demand probability distributions versus the corresponding Poisson (left) and Normal (right) distribution functions, it was confirmed that the Poisson distribution yielded the best fit for the procedure demand data. The fit of the data in the plots was calculated by means of an R^2 -value which is displayed left of the respective graphs.

Table 9. The results of the parametric distribution fitting. As can be seen in the results the Poisson distribution outperforms the Normal distribution across the board but the discrepancy becomes most notable for lower average demand values.

Procedure	Parameters		Normal fit (R^2)	Poisson fit (R^2)
	Average (λ or μ)	Standard deviation (σ)		
Blaas TURT	3.43	1.91	0.9820	0.9978
Prostaat TURP	1.88	1.59	0.9473	0.9932
Blaas suprapub.	0.43	0.62	0.7208	0.9973
Prostaat bioptie	0.15	0.42	0.3407	0.9686
Overall	15.39	6.20	0.9818	0.9848

5.2.2. Building the forecasting model

In this section we explain how we want to build the forecasting model. In the previous section we demonstrated that Poisson distribution gave the best fit for the procedure demand data. An additional advantage of having Poisson distributed demand is that, under the assumption that the demand for different procedures is statistically independent, the sum of the demand for multiple procedures is Poisson distributed as well [52]. This principle will prove crucial to forecast tray demand based on past procedure demand. After all, if one knows which trays are requested for which procedure, one can obtain a Poisson distribution for the instrument trays by summing the demands of the respective procedures.

In order to calculate the demand per tray we decided to generate a cross table which specifies the relationship between the procedures and the requested trays per procedure. This cross table is then subsequently used to translate the demand per procedure into a demand per instrument tray type. An example of how this is done is demonstrated by introducing a toy problem. Say we have a urology department which only conducts three procedures (Blaas TURT, Prostaat TURP and Blaas biopten) and does so by using three instrument trays (OLVG Bi-polair tur set, OLVG Maatbeker 1000 ml and OLVG maatbeker 3000 ml). In that case the cross table might look as shown in table 10. When assuming that the occurrences of these procedures are statistically independent the Poisson λ per instrument tray (λ_T) can be calculated by summing the products of the cross table coefficients with their respective Poisson λ values (formula 3).

Formula 3.
$$\lambda_T = \alpha\lambda_\alpha + \beta\lambda_\beta + \gamma\lambda_\gamma$$

Table 10. A toy problem demonstration using three procedures: “Blaas TURT”, “Prostate TURP” and “Blaas biopten”.

	Blaas TURT (α)	Prostate TURP (β)	Blaas biopten (γ)
OLVG Bi-polair tur set	1	1	1
OLVG Maatbeker 1000 ml	1	0	1
OLVG Maatbeker 3000 ml	0	1	0
Poisson λ	3.43	1.88	0.30
	OLVG Bi-polair tur set	OLVG Maatbeker 1000 ml	OLVG Maatbeker 3000 ml
Poisson λ_T	5.61	3.73	1.88

In figure 11 we provide an example of how we generated the final cross table. This was done by comparing the amount of procedures to the amount of requested trays for that procedure (*sheet “Instrument demand calculation”*). If the amount of requested trays was close to the amount of procedures it was assumed that the tray is requested for this surgery by default. For this operation a deviation of 10 to 15% was allowed when comparing the procedure frequency to the amount of requested trays. Unfortunately this way of generating a cross table is no exact science and in contrast to the example in figure 11 some of the tray lists were not as unambiguous as in the given example.

☐ Penis circumcisie kind	22	Instrumentennetten per protocol	
☐ OLVG Chirurgisch net	1	Row Labels	Penis circumcisie kind
☐ (blank)	1	OLVG Hem-o-lok cliptang L	
☐ (blank)	1	OLVG Hem-o-lok cliptang ML	
☐ OLVG Klein urologisch setje VOORRANGSNET	21	OLVG Klein chir. net	
☐ (blank)	21	OLVG Klein urologisch setje VOORRANGSNET	1
☐ (blank)	21	OLVG Klein Vaginaal Netje	
		OLVG L.A.V.H. set	
		OLVG Lampendop OK ALG VOORRANG	
		Grand Total	22

Figure 11. An example of how the cross table was generated. In the surgery tray list (left) it can be seen that the procedure “Penis circumcisie kind” was executed 22 times over the predetermined time span. During this time, 1 procedure was conducted using “OLVG Chirurgisch net” and 21 were conducted using “OLVG Klein urologisch setje VOORRANGSNET”. It was therefore assumed that using “OLVG Klein urologisch setje VOORRANGSNET” is common practice to perform the procedure “Penis circumcisie kind”.

Utilizing the average demand values of the 25 most frequently conducted procedures we were eventually able to obtain a Poisson λ for 29 different tray types varying between 0.1 and 8.9 (supplement 4). In further analysis these values were used to estimate the upper boundary of the 97.5% demand confidence interval by utilizing the parametric Poisson distribution as introduced in section 5.1.2 (*sheet “Req. trays sterilization cycle”*). From this 97.5% upper boundary of weekly demand, a supply recommendation can be calculated by dividing the amount of weekly required trays by the sterilization rate of the central sterilization services department (CSSD). In short this sterilization rate is the amount of trays that the CSSD can sterilize of a given tray type within a work week. Assuming that the facility is operational on a 24/7 basis this rate is calculated by dividing the 168 operational hours by the lead time (LT) per instrument tray type. Here the lead times are 6, 15 or 34 hours depending on the tray sterilization priority, as outline in table 4 of section 4.3.

5.3. Determining the validity and accuracy of the forecast model

In sections 5.1 and 5.2 we described how a tray forecast model can be generated based on the previous procedure demand as documented in the EPF dataset. Here the aim of the forecast model was to give a correct estimation of the instrument tray supplies required to cover **97.5% of the possible instrument tray demand**. This supply estimation was calculated in the excel file *Demand prediction.xlsx*; *sheet “Req. trays sterilization cycle”*. In this section we validate this model and calculate the forecasting accuracy. For the model validation, conducted in section 5.3.1, we have chosen to compare the outcomes of the demand forecasting model to the instrument throughput which was recorded in the 10 week training dataset. In this way we can determine if the forecast model closely approximates the demand values which we used as an input for the model. Model accuracy on the other hand was calculated by examining the forecasting error in section 5.3.2.

5.3.1. Validating the forecasting model

In this section we validate the demand forecasting model as proposed in section 5.1 and 5.2 (*Prediction validation.xlsx sheets “Comparison count vs prediction” and “Comparison count vs weekly prediction”*). In order to do so we compared the demand forecasts to the recorded demand in the model training dataset in order to determine if the forecasting model closely approximates 97.5% of all possible demand during the training period. Recall from section 5.2 that this dataset entails the first 10 weeks of the EPF dataset

which records all conducted procedures for the Urology department and all the instruments necessary to conduct these procedures.

Let us now compare the recorded demand in the 10 week training dataset to the forecasted demand according to the forecasting model. If we look at the measured results over the 10 weeks training dataset, we can see that the EPF has registered a demand of 749 trays over 84 different tray types (*sheet “Comparison count vs prediction”*). As mentioned in section 5.2.2, however, our forecasting model was able to forecast a demand for only 29 different tray types. For this reason we chose to label these 29 different tray types as “Predicted” tray types, whereas the remaining 55 tray types are labeled as “Unpredicted” tray types. When we look at the overall results, we found that 82.38% (or 617) of the 749 requested trays was covered by the 97.5% confidence intervals (figure 11). If attention is focused solely on the predicted tray types it can be seen that this value rises to 94.78 %. This is unfortunately about 3% less than the intended 97.5%.

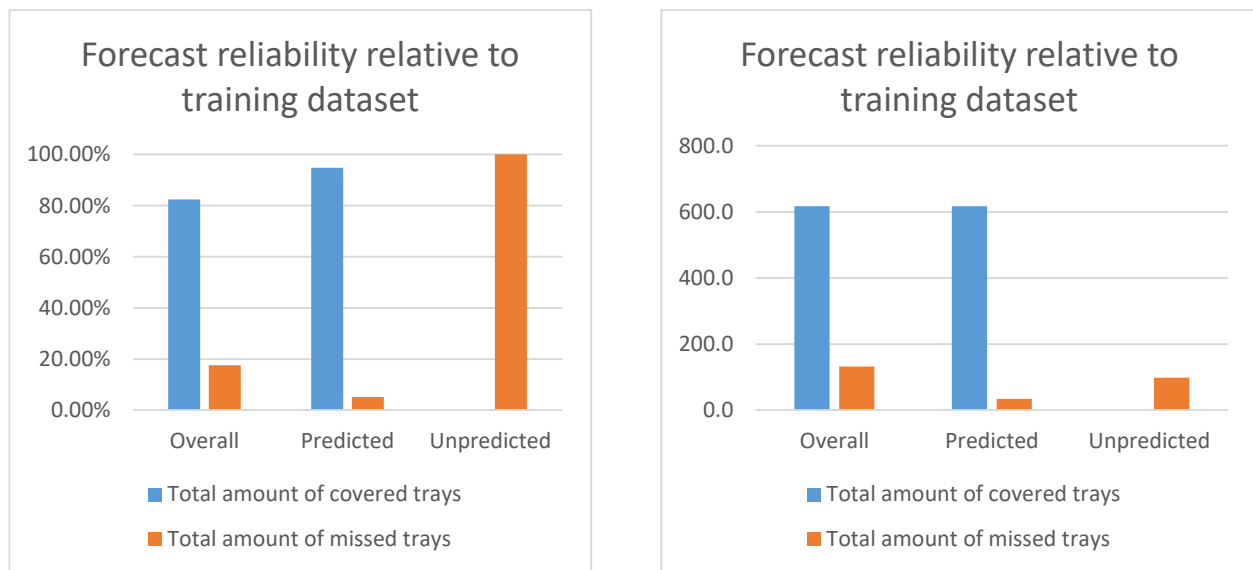


Figure 11. Tray demand in percentage (left) and absolute (right) values. Next to the overall values a distinction was made between tray types for which a demand was predicted (λ -values higher than 0) and tray types for which a demand was not predicted (λ -values equal to 0).

If we focus on the demand per specific tray type, especially the results for “CYSTOSCOPIE 22.5 FR 12° 30° OK URO” were remarkable. For this tray type a demand of 39 trays was recorded while the forecast model only predicted a 97.5% confidence upper bound of five trays. The reason why this happens was found in the generation of the cross table in section 5.2.2. For the generation of the cross table we have only taken into account which trays are most likely to be ordered per procedure. The “CYSTOSCOPIE 22.5 FR 12° 30° OK URO” tray, however, was one of the most common pieces of back-up equipment if the standard surgery order protocol was not followed.

Besides this extreme example, five other tray types were found in which the tray demand falls in the top 25th percentile of the forecasted 97.5% confidence interval. In most cases this could be explained by the fact that these tray types are commonly used for infrequent procedures. They are therefore harder to predict because the uncertainty in the estimation is higher. Another explanation might be that these trays

are commonly used as a second option for certain procedures, similar to the “CYSTOSCOPIE 22.5 FR 12° 30° OK URO” example.

Next to an analysis over the full 10 week training period we also compared the output of the forecast model to the demand recorded in the EPF dataset on a week by week basis (*sheet “Comparison count vs weekly prediction”*). In table 11 we can see how many tray types there are in which the demand surpasses the 97.5% confidence interval for a specific amount of weeks. If we for example look at the 29 predicted tray types, we can see that for roughly 14% of these tray types, demand surpasses the supply for at least 1 week. Of this 14%, only half of the tray types (7%) surpass the confidence interval for at least two weeks.

Table 11. Summary of the week by week comparison. This table summarizes the amount of trays that surpass the predicted confidence interval for a specific amount of time. For the predicted tray types, roughly 14% of the different tray types surpass the confidence interval for at least 1 week. Looking at the unpredicted tray types this percentage rises to 87%.

Number of weeks higher than 97.5% confidence interval	% Of predicted tray types	Amount of predicted tray types	% Of unpredicted tray types	Amount of unpredicted tray types
1 week	13,79%	4	87.27%	48
2 weeks	6,90%	2	29.09%	16
3 weeks	3,45%	1	25.45%	14
4 weeks	3,45%	1	7.27%	4
5 weeks	3,45%	1	5.45%	3
6 weeks	3,45%	1	1.82%	1
7 weeks	3,45%	1	0.00%	0
8 weeks	3,45%	1	0.00%	0
9 weeks	0,00%	0	0.00%	0
10 weeks	0,00%	0	0.00%	0
Measured time period		10 weeks		
Total amount of tray types included in forecast		29 tray types		
Total amount of tray types not included in forecast		55 tray types		

5.3.2. Determining forecasting model accuracy

In addition to model validation we also attempted to determine the forecasting accuracy. In contrast to section 5.3.1 this was not done introspectively by examining the difference between forecast and training data but extrospectively by comparing the forecast to new data in the four week testing dataset. Recall from section 5.2 that this testing dataset entails the last four weeks of the 14 week EPF dataset, whereas the training dataset encompasses the first 10 weeks of this dataset. Here the EPF dataset in general records all conducted procedures for the Urology department and all the instrument necessary to conduct these procedures.

Generally speaking forecasting accuracy can be determined by a large variety of methods, in which most compare the forecasted values to the recorded values to calculate the forecasting error [55]. Here the use of forecasting errors can for example be convenient to compare multiple forecasting methods on the same dataset. Important examples of such methods are the mean squared error, the root mean squared error

and the mean absolute error [55]. Using such accuracy measures to judge the forecasting accuracy in an absolute sense, however, is rather difficult because the magnitude of the error is not put in perspective to the magnitude of the forecasted and/or measured values. These accuracy measures are therefore called scale dependent accuracy measures.

To be able to put forecasting errors in perspective, popular methods usually express the obtained forecasting error as percentage errors. One of the most important examples of such a method is the Mean Absolute Percentage Error (MAPE) which can be described according to formula 4 [56]. Here Y_t and F_t stand for the demand (Y) and forecasted demand (F) that were obtained for time t. The sample size T denotes the number of weeks in our testing dataset which ranges from one to four as described earlier in this section.

Formula 4.
$$MAPE = \frac{1}{T} \sum_{t=1}^T \left(\left| \frac{Y_t - F_t}{Y_t} \right| \right) * 100\% \text{ with } T = 1, 2, 3, 4$$

As can be seen from the formula MAPE percentualizes the forecasting error by dividing the forecasting error by the observed demand. When we look at the recorded demand (**sheet “Comparison count vs weekly prediction”**), however, we can see that we are currently faced with intermitted demand. With demand values coming close to zero this means that the MAPE accuracy measure will approach infinite percentual errors which distorts an accurate view of the obtained absolute accuracy [56].

To overcome these issues we propose to use a scaled error instead of a percentual error. This can be achieved by utilizing the Mean Absolute Scaled Error (MASE) as described in the Hyndmann 2006 paper [55]. Here the MASE compares the forecasting error of one method to the in-sample forecasting error of a reference forecasting method. Utilizing MASE we can distinguish three possible conditions. In the case that $MASE = 1$ we can say that the error of the selected forecasting method equals the forecasting error of the reference method. For $MASE < 1$ the error of the selected forecasting method is significantly smaller than the error of the reference method. Last, if $MASE > 1$ the error of the selected forecasting method is significantly larger than the error of the reference method.

To calculate the MASE we can utilize formula 5. Here Y_t and F_t stand for the demand (Y) and forecasted demand (F) that were obtained for time t. The sample size T denotes the number of weeks in our testing dataset which ranges from one to four as described earlier in this section. The E_{Ref} constant is the reference error by which the forecasting error ($Y_t - F_t$) is compared. To calculate the MASE for our Poisson based forecasting model we therefore have to establish a meaningful reference forecasting method.

Formula 5.
$$MASE = \frac{1}{T} \sum_{t=1}^T \left(\left| \frac{Y_t - F_t}{E_{Ref}} \right| \right) \text{ with } T = 1, 2, 3, 4$$

As explained in section 5.2.2 we utilized a cross table (table 10), to calculate the average instrument tray demand based on the average procedure demand. The obtained average instrument tray demand was subsequently used as an input to generate the corresponding Poisson distributions and calculate the 97.5% confidence intervals. Recall from section 5.1.1 that the reason for utilizing past procedure demand for tray demand forecasting instead of using past instrument throughput, was that we projected this to have practical as well as administrative advantages. It would therefore be interesting to see if our cross table method would yield more accurate forecasting results relative to the utilization of past tray throughput.

To investigate this, a second forecast was created by averaging the recorded instrument trays throughputs over the 10 week training dataset. This average tray throughput was then utilized in the Poisson distribution to calculate a second set of 97.5% confidence intervals. The upper boundaries of the second set of 97.5% confidence intervals were then compared to the recorded throughputs in the four week testing dataset, in order to obtain a reference forecasting error. This reference error was calculated according to formula 6. Here Y_t and Ref_t stand for the demand (Y) and the reference forecast (Ref) that were obtained for time t. Recall that the sample size T here stands for the number of weeks in our testing dataset as well.

Formula 6.
$$E_{Ref} = \frac{1}{T} \sum_{t=1}^T (|Y_t - Ref_t|) \text{ with } T = 1, 2, 3, 4$$

Given the formulas for MASE and E_{Ref} , we can now calculate the MASE for our cross table based forecast relative to a direct instrument throughput based forecast. To demonstrate how this was done let us consider the following example (table 12). Here we can see that we have recorded demands for four weeks for the “Cystoscopy 30° OK URO” and “OLVG Maatbeker 1000 ml”. For these given tray types, the forecasts according to the cross table method can be found in column Forecasts (F_t) and the reference forecast can be found under Reference forecast (Ref_t). If we use formula 6 on the given data we can calculate that the E_{Ref} for “Cystoscopy 30° OK URO” equals $\frac{1}{2} * (|5 - 8| + |3 - 8|) = 4$. With an E_{Ref} of 4 the MASE therefore becomes $\frac{1}{2} * \left(\left| \frac{5-1}{4} \right| + \left| \frac{3-1}{4} \right| \right) = 0.75$. In analogy to these calculations, the E_{Ref} and MASE for “OLVG Maatbeker 1000 ml” where determined to be 6.5 and 1.15 respectively.

Table 12. An example for a MASE calculation based on two tray types for a dataset that includes two weeks of data.

Instrument tray type	Week 1	Week 2	Forecast (F_t)	Reference forecast (Ref_t)
CYSTOSCOPIE 30° OK URO	5	3	1	8
OLVG Maatbeker 1000 ml	3	4	11	10

Instrument tray type	E_{Ref}	ASE Week 1	ASE Week 2	MASE
CYSTOSCOPIE 30° OK URO	4	1.00	0.50	0.75
OLVG Maatbeker 1000 ml	6.5	1.23	1.08	1.15

To get an idea of the overall accuracy of our cross table based forecasting method, we chose to report the averaged MASE values over all instrument tray types, together with the corresponding standard deviation. The overall results of the MASE analysis are summarized in figure 12. Here we can see that our cross table based forecasting model has a slightly smaller forecasting error for the 29 predicted instrument tray types relative to the forecast based directly on average tray throughput (MASE = 0.93). For the 55 unpredicted tray types, however, the forecasting error was notably smaller (MASE = 0.45). In operational terms the latter phenomenon means that it is more likely to have no demand for these 55 instrument tray types than a very low demand based on a recorded demand average.

Unfortunately the forecasting errors for both predicted and unpredicted instrument tray types do not significantly differ from our reference method when taking the calculated standard deviations into consideration. This conclusion was reached because the standard deviations surpass the $MASE = 1$ value. This means that based on the variance in the obtained MASE values, the real MASE for our forecasting method can be higher as well as lower than 1.

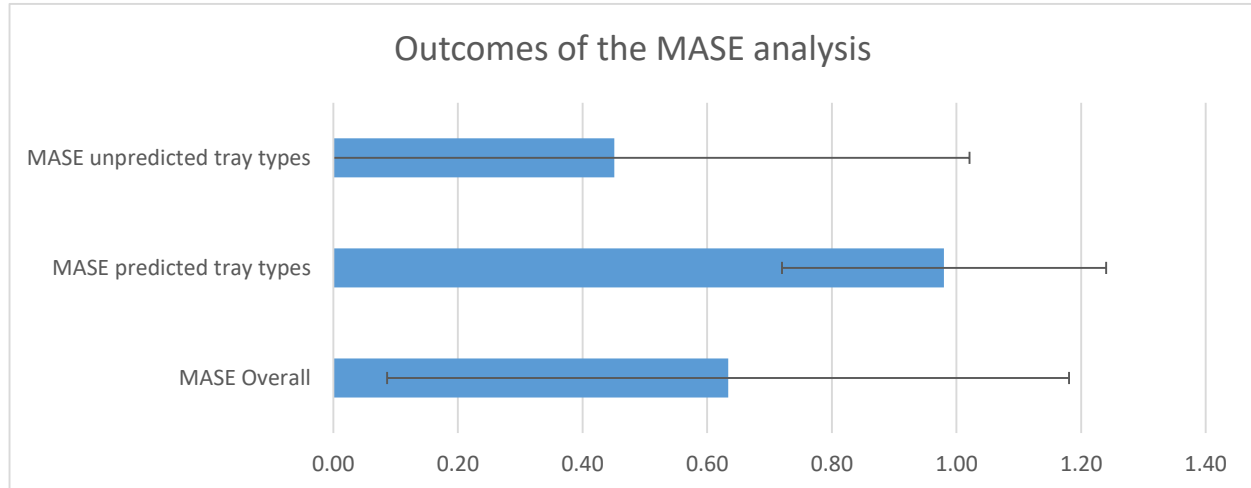


Figure 12. The results of the MASE analysis for the stochastic forecasting model. For this MASE analysis the forecasting errors were compared to the forecasting errors of a reference method. For MASE analyses we distinguish between $MASE = 1$, $MASE < 1$ or $MASE > 1$ which indicates that our forecasting error is either equal, smaller or greater than the forecasting error of the reference method.

If we look at the MASE values for individual trays (*sheet "MASE"*), we can see that this large variance can be attributed mostly to instrument tray types which are frequently used on weekly basis (more than 10 times per week). Here the forecasted values tend to overestimate the actually recorded demands. The exact reason why this happens needs to be investigated more closely.

5.4. Discussion

In chapter 4 we emphasized the necessity to radically improve the planning functions of the instrument sterilization cycle. To do so, we argued that the use of past demand to forecast future demand would be a relatively attractive attribute. This is caused by the fact that a direct MRP planning, based on the scheduled surgeries, would be difficult to achieve because the surgery schedule is subject to continuous changes (section 3.1.2). To generate a forecast of future demand we proposed to make use of a stochastic forecasting model. We supposed that such a model would be relatively easy to use because the empirical data can be fitted to parametric distributions which allow for statistical extrapolation of the original data. In the current chapter we proposed to build such a model as a proof of principle, by coupling the demand for specific procedures to the demand for corresponding instrument trays. Here the utilization of procedure demand was thought a convenient input parameter because it is commonly used for healthcare dimensioning in other situations as well [5], [43].

Based on the stochastic forecasting model we hoped to achieve the following two goals:

1. Estimate the amount of instrument trays required to cover 97.5% of the possible instrument tray demand.

2. Give a generalized idea of how the compilation of surgery order protocols should be adjusted to influence the amount of instrument tray supplies and instrument tray demands.

As a consequence we chose to sub-divide the discussion into three separate parts, in section 5.4.1 and 5.4.2 we reflect on the two aforementioned goals. In section 5.4.3 we finish off with providing some general remarks regarding the use of the forecasting model.

5.4.1. Covering 97.5% of the possible tray demand

In this section we investigate whether our model could provide an accurate enough estimation to cover 97.5% of all possible instrument tray demand. As described in section 5.3.1 the forecast model was able to predict a demand for 29 out of the 84 different tray types. If we examine the validity of the forecasting model for the 29 predicted tray types, we can say that the model provides a reasonably valid representation of the real situation. Overall, 94.78% of the tray requests were covered by the forecast compared to a 97.5% intended coverage by the confidence interval. When examining the tray types individually, roughly 14% of the 29 tray types surpassed the confidence interval at some point over the course of the 10 week training period, but 7% did so for just 1 week.

The forecast results from our prediction model were also tested for forecasting accuracy. This was done by calculating a MASE ratio between the forecast errors of our forecasting method and a reference forecasting error obtained from a reference forecasting method. Here the reference forecasting method was based on the average tray throughput over the 10 week training dataset. Based on a calculated MASE of 0.98 +/- 0.26 for the 29 predicted tray types and a MASE of 0.63 +/- 0.55 over all 84 different tray types, we can conclude that our cross table based forecasting model offers a forecasting accuracy equal to the utilized reference method. The fact that we did not find a significant difference in forecasting accuracy might be caused by the small testing dataset which we utilized for accuracy testing in section 5.3.2. For future reference it might therefore be worth investigating, whether significant results can be obtained through the utilization of a larger testing dataset.

The results as described above, of course partially disregard the 55 tray types for which no demand was forecasted. If we look at the overall results for the model validation we can see that over the recorded demand of 749 instrument trays in the training dataset, only 617 trays (82.38%) were covered by the total prediction model. The fact that so many trays are presently disregarded by the forecasting model is likely caused by our model design which was explained in section 5.2.1. Here we chose to only include the 25 most frequently conducted procedures out of the possible 93. This top 25 was selected according to the Pareto principle which states that roughly 20% most frequent procedures account for 80% of all instrument tray demand.

To investigate the extent to which adding more procedures can increase the model's validity for all tray types, we conducted an additional investigation. In this investigation we expanded our model to include the top 38 of most conducted procedures, which constitute 90% of the overall demand (supplement 5 and **Prediction validation90.xls sheets "Comparison count vs prediction", "Comparison count vs weekly prediction" and "MASE"**). By doing so, the amount of trays for which demand is forecasted rises from 29 to 38 out of 84. Similarly, the overall amount of tray orders covered by the prediction increases from 82.38% to 85.98%. More remarkable results can be found when examining the trays on an individual basis. Where in the previous model 7% of the 29 tray types surpassed the confidence interval supply for at least two weeks, this number drops to roughly 2.5% for the 38 tray types in the revised model. A similar decrease was noted for the unpredicted trays. Where in the previous model 16 out of the 55 tray types (29%)

surpassed the confidence interval supply for at least two weeks, this number drops to roughly 7 out of the 46 tray types (15%) in the revised model.

If we then shift our attention to the MASE analysis for this new model, the image of improved forecasting is confirmed. Here we see that the MASE drops from 0.98 to 0.93 (+/- 0.33) for predicted trays and from 0.45 to 0.39 (+/- 0.59) for unpredicted trays. We can therefore cautiously conclude that adding more procedures to the prediction model would improve its accuracy. What remains to be determined, however, is whether the benefit of higher accuracy outweighs the effort of adding the remaining majority of procedures to the forecasting model.

5.4.2. Influencing instrument tray supplies and demand

With our model in mind, let us now look at how surgery order protocol compilation can be used to influence the amount of instrument tray supplies and instrument tray demand. Here the question of “are we using the trays that we should be using?” plays a central role. To investigate this question, let us first recapitulate what we have learned about tray and order protocol compilation so far.

In section 3.1 we described the current pragmatic way in which instrument trays and order protocols are compiled from a clinical perspective. From the interviews on which this section was based, we can conclude that the medical personnel has a high degree of freedom when it comes to the selection of the right tools for the job. In the view of the staff, the role of a medical specialist or an OA (instrument specialist) has to be seen as a craft or trade which requires a specific set of skills. In these roles a strong medical expertise, a feel for the patient’s needs and a certain flexibility regarding the selection of an optimal treatment are indispensable.

Due to the importance of the major health and security aspects involved in the work of medical staff we opine that the initiative for clinical decision making should always have clinical experts in the lead. The compilation of instrument trays and surgery order protocols is such as decision. This does not mean, however, that a central management authority cannot influence the decentralized decision making process. Instead of an imposed optimization and standardization from the top down, we therefore propose to formalize the decision making process that lies at the foundation of instrument tray and order protocol compilation. Here a centralized management authority can influence the decision making process described in 3.1, by imposing restrictions, creating incentives and empowering staff members [18], [58]. Here an optimized version of the prediction model can be used to achieve staff empowerment because it has the potential to form a platform for informed debate.

To clarify this statement let us look at the following examples of the (intermediate) results displayed in section 5.2 and 5.3:

- 1) From the description of order protocols and instrument trays in section 3.1 one might argue that surgery order protocols provide a clear-cut directive for which tray subsets are to be used for a specific procedure. In practice, however, the relationship between a subset of trays and a procedure is not as unambiguous as one might hope (figure 13). For this reason we used a relatively empirical method to establish these relationships for our model in section 5.2. Examples as seen in figure 13 can therefore serve an informative role in the aim of standardizing work processes. Here questions should be asked like; “why do we do what we do?” and “can this be done more efficiently?”. Of course the answer to the latter question can be a “substantiated no” but it is questions like these that will help keeping the medical staff sharp.

☐ Nier pni	22	☐ Ureter jj-catheter inbrengen	11
☐ OLVG Klein urologisch setje VOORRANGSNET	22	☐ OLVG Cysto-Uretheroscoop 30° VOORRANGSSET	8
☐ OLVG Cysto-Uretheroscoop 30° VOORRANGSSET	20	☐ OLVG Verwijdertang dubbel J cath.	8
☐ OLVG PNL net extra lang	20	☐ OLVG Basis net	1
☐ OLVG PNL Paktangen	20	☐ OLVG Lampendop OK ALG VOORRANG	1
☐ OLVG Optiek 30° P.URO	6	☐ OLVG Laparotomie net	1
☐ OLVG Verwijdertang dubbel J cath.	6	☐ OLVG URS net VOORRANGSSET	1
☐ OLVG PNL net	6	☐ (blank)	1
☐ OLVG Litho Clast net	6	☐ OLVG URS net VOORRANGSSET	7
☐ OLVG URS net VOORRANGSSET	6	☐ (blank)	7
OLVG Lithoclast Trilsondes	6	☐ OLVG Verwijdertang dubbel J cath.	1
☐ OLVG Verwijdertang dubbel J cath.	14	☐ OLVG Optiek 30° URO	1
☐ OLVG PNL net extra lang	2	☐ OLVG URS net VOORRANGSSET	1
☐ OLVG PNL Paktangen	2	☐ (blank)	1
☐ OLVG Optiek 30° URO	2	☐ OLVG Werkscoopnet 1/2	2
☐ OLVG PNL net	2	☐ OLVG Werkscoopnet 2/2	2
☐ OLVG Litho Clast net	2	☐ OLVG L.A.V.H. set	2
☐ OLVG URS net VOORRANGSSET	2	☐ OLVG MyTube	1
☐ OLVG Lithoclast Trilsondes	2	☐ OLVG Dilatoren set DC	1
☐ (blank)	2	☐ OLVG Uterus manipulator VOORRANGSSET	1
		☐ OLVG 30° graden optiek 10 mm Stryker	1
		☐ (blank)	1
		☐ (blank)	1
		(blank)	1
		☐ OLVG Uteruskantelaar+conusopzetstuk OK GYN	1
		☐ OLVG Uterus manipulator VOORRANGSSET	1
		☐ OLVG 30° graden optiek 10 mm Stryker	1
		☐ (blank)	1

Figure 13. Examples of requested trays per procedure lists where it is hard to determine which trays are used for which surgery by default.

- 2) Another example for a source of debate can be generated by retrospectively comparing the cross table introduced in section 5.2.2, to the surgical order protocols (***Demand prediction.xls; sheet "Instrument demand calculation"***). In the case of the procedure "prostate millin" for example, "OLVG Urologisch net" is commonly exchanged for "OLVG Urologisch net extra lang". For the procedures "Nier urs niersteen" and "Ureter urs diagnostisch", on the other hand, "OLVG Optiek 30° URO" is commonly added to the tray list as an additional piece of equipment. Adjusting the surgical order protocols based on these finding should be relatively straight forward.
- 3) The last example that we will give can be found in the results from section 5.3 (***Prediction validation.xls sheets "Comparison count vs prediction" and "Comparison count vs weekly prediction"***). In this section we concluded that if we focus on the demand per specific tray type, especially the results for "CYSTOSCOPIE 22.5 FR 12° 30° OK URO" were remarkable. For this tray type the recorded demand was significantly higher than what was expected based on the forecast. This is most likely caused by the fact that this tray is one of the most common pieces of back-up equipment if the standard surgery order protocol was not followed. Here it would be interesting to investigate why this piece of equipment is used so frequently as a back-up tray. Here examples of appropriate questions to ask can include the following:
 - Are the supplies for the default trays not sufficient enough?
 - Do the default trays lack functionality?
 - Should "CYSTOSCOPIE 22.5 FR 12° 30° OK URO" be used as a default tray instead?

- For which procedures can this switch in default trays result in a safer, more effective treatment?
- For which procedures can this switch in default trays result a more (cost) efficient solution?

5.4.3. General remarks

At the start of this section we summarized the potential advantages of utilizing a stochastic forecasting model to improve the instrument sterilization cycle. When reviewing the outcomes of the current chapter, however, we can also highlight some significant drawbacks of the approach that we utilized for this thesis. In section 5.2 for example we found that the use of procedure probability to predict tray demand can become laborious when large amounts of procedures and corresponding trays are involved. Here we only tried to generate the model for a single specialism which only includes a fragment of all the procedures and instrument trays used at OLVG. In addition to the vastness of the work involved in generating the forecasting model, it can sometimes prove hard to determine which trays are used for which procedure by default. As a result, we could conclude in section 5.3 that the use of a forecasting model is not always inclusive for all tray types. This was especially highlighted by the results of the forecast for the tray “CYSTOSCOPIE 22.5 FR 12° 30° OK URO”.

We would therefore like to recommend that the generation of this forecasting model will be conducted in a more facile way, for example by using a more automated software environment. Another possibility for simpler demand forecasting can be achieved by applying the current stochastic approach directly to measured throughput data of the sterilization cycle as done for the MASE comparison. Although much easier to implement, such a direct forecasting model would have the obvious disadvantage of not providing insight in tray utilization per procedure. The most likely candidate to provide good quality throughput data at this point would be the T&T system employed by the CSSD facility. As of September of this year, Clinium CSSD has started to increase its focus on this type of forecasting and was therefore willing to provide a new dataset that can be readily adopted for Poisson forecasting. Before using such datasets in a clinical context at OLVG, however, the discrepancies between the monitoring systems observed in section 4.2.2 will have to be investigated and resolved. Up to this point it remains unclear why and how these discrepancies occur and how they should be resolved.

5.5. Conclusion

In chapter 4 we emphasized the necessity to radically improve the planning functions of the instrument sterilization cycle. To do so, we argued that the use of a stochastic forecasting model could offer an appropriate starting point. In sections 5.2 and 5.3 we proposed to build such a model as a proof of principle. This was done by coupling the demand for a selection of conducted procedures to the demand for the corresponding instrument trays. Based on the stochastic forecasting model we hoped to achieve an accurate estimate of the amount of instrument trays required to cover 97.5% of the possible instrument tray demand. Furthermore, we hoped that the generation of the model would provide some additional insight into the impact that adequate surgery order protocol compilation would have on the amount of instrument tray supplies required to service the sterilization cycle.

For the investigation in this thesis we chose to build the instrument tray demand forecasting model, based on the demand for 25 procedures out of the possible 93 procedures for the Urology department at OLVG. After discussing the results of section 5.3 we were able to conclude that this forecasting model does not offer a valid representation of the actually recorded instrument tray demand for all instrument tray types.

By utilizing the top 25 procedures we were able to predict a demand for 29 out of the 84 possible tray types. Using the forecasts for these 29 tray types we were able to cover 82.38% of all possible tray demand opposed to the intended 97.5%. If we shift our attention to the forecasting accuracy, we found that our forecasting model based on past procedure demand was just as accurate as a forecast based directly on past tray throughput. This conclusion was reached based on a mean absolute scaled error (MASE) analysis, where a MASE of 1 indicates an equal ratio between a forecast error and a reference error. For our MASE analysis values of 0.98 ± 0.26 were observed for the 29 predicted tray types whereas the MASE values averaged 0.63 ± 0.55 over all 84 different tray types.

In section 5.4.1 we found that it is possible to improve the stochastic forecasting model by including more procedures to the forecasting model. Given the vastness of the work involved, however, it remains to be determined whether it is worth the effort to expand this model in its current form. In section 5.4.3 we therefore offered that a different software platform could be used to automate demand forecasting as it was done in this thesis. Furthermore, we offered that an easier forecasting method could be generated based directly on the instrument tray throughput data of the central sterilization services department (CSSD). This can only be done under the condition that the reliability of the CSSD data is verified.

What this model does offer is a way to look into order protocol composition. From the description of order protocols and instrument trays in section 3.1 one might argue that surgery order protocols provide a clear-cut directive for which tray subsets are to be used for a specific procedure. In practice, however, the relationship between a subset of trays and a procedure is not as unambiguous as one might hope. The uncertainty in this relationship can be reduced by looking to the procedure frequency versus tray request data as demonstrated in section 5.2. Here deviations in practice can be utilized to inform the medical staff which empowers them to make the right decisions for order protocol adjustment.

6. Devising an information management strategy

In chapter 4 we concluded that the OLVG East sterilization cycle can be characterized as a make to stock (MTS) supply chain with a severely impaired control mechanism. To restore the control mechanism we hypothesized that our main challenge would be to promote managerial attention towards the tactical planning functions. In order to do so, we argued that the use of a stochastic forecasting model could offer an appropriate starting point. In chapter 5 we therefore proposed to build such a model as a proof of principle. This was done utilizing the EPF throughput data of the sterilization cycle accompanied by the patient centered performance measures established in sections 4.1.2 and 4.2.1, as input measures. Based on these input measures we coupled the demand for a selection of conducted procedures to the demand for the corresponding instrument trays.

After discussing the results of chapter 5 we were able to conclude that it is possible to generate a forecasting model based on the aforementioned parameters. The accuracy of the current proof of principle model, however, was not sufficient to satisfy the functional demands. The model in itself allows for further improvement, but as an alternative we also proposed that direct throughput data provided by the CSSD can be utilized for forecasting as well. By doing so at this point in time, however, the model would be faced with the data discrepancies as encountered in chapter 4 section 2.2. For this reason we have to consider if the implementation of the aforementioned forecasting model should be accompanied by fundamental changes to the IT environment that is currently in place. This will be done in the current chapter in order to answer sub-question 4. Here a strong emphasis is put on the possibilities for T&T technology due to the interest expressed by the OLVG as mentioned in chapter 1 section 2.

To give an introduction in what T&T is and what can be achieved by its implementation section 6.1 provides a brief overview of the developments in T&T in other industries. In section 6.2 we give an overview of the deficiencies of the current IT environment as encountered in the previous chapters. These deficiencies are subsequently addressed in a final redesign of the ground form of the sterilization cycle. In section 6.3 we follow up on this redesign by looking at the available technologies to realize a functional T&T environment.

6.1. An overview of automated track and trace in supply chains

As explained in section 5.1.2, the healthcare providing industry can be regarded as a laggard industry when it comes to the implementation of new ideas or technologies like T&T [49]. For this reason it is interesting to draw parallels with other industries that have already been through similar changes. Over the course of this thesis we have discovered that the operational nature of this master's assignment closely borders to supply chain management, which covers subjects like product consumption planning, raw materials sourcing, transport and warehousing [59]. In supply chain management research, a growing body of evidence discusses the potential quality benefits which would result from the application of highly detailed T&T capabilities. To obtain a better understanding of what this discussion entails, section 6.1.1 briefly describes what T&T is and how it has evolved in a supply chain context. To get an image of what T&T might mean in a clinical environment, section 6.1.2 provides a brief overview of the impact of T&T in allied industries.

6.1.1. A brief history of automated track and trace

Let us now first focus on the development of T&T in a supply chain context. T&T systems are systems that can be used to identify and register products in a supply chain on an individual basis [60]. By doing this with an accurate location and time indication it enables supply chain managers to follow the progress of a product through the supply chain. In this perspective "Tracking" refers to the planning of the projected

path of an item through the supply chain whereas “Tracing” refers to a reverse monitoring process of the item’s historical whereabouts [60]. T&T systems are therefore potent tools for continuous quality monitoring because the quality of a process can always be coupled to the quality of a product.

Technologies for simple and fast product identification have been under development since the second half of the 20th century. In the early 1950s, Norman Joseph Woodland developed and patented the 1-dimensional standard barcode which became commercially successful with the broad implementation in the retail markets in the 1970s [61], [62]. The 1D-barcode can be described as a linear data array of which the coding sequence is translated into a scannable sequence of black and white lines [63]. Over the years, the need to store more information into a single barcode, combined with the limited data content of linear barcodes, resulted in the development of 2D barcode technologies in the late 1970s [64].

The broad scale adoption of 2D-barcodes took flight in the early 2000s partly promoted by the impulse of e-commerce and the availability of high resolution mobile camera technology [65]. A popular example of 2D-barcodes is the so-called Quick Response code or QR-code which can be discerned by its concentric square patterns on the corners of the barcode to facilitate barcode read-out. These QR-codes should not be confused with, or used in parallel with, so called Unified Device Identifier (UDI) data-matrix standards, which will be addressed later this chapter. Here the looks of these two standards are similar but where QR-codes can be used for various applications, the more sophisticated UDI-codes have been strictly developed for healthcare related purposes [66].

During the same time period a competing standard based on radio frequency communication saw its rise to popularity as well. Traditionally, Radio Frequency Identifier (RFID) technology is a labeling technology that makes use of small data chips connected to passive RF transmitting antennas which transmit the ID information when activated with an RFID scanning device [67]. In 2008 this passive technology had a reported storage capacity of roughly 4 kB which was on par with the reported highest standards in 2D-barcoding a year earlier [65], [68]. More recently developed RFID standards, however, incorporate a power source that can last for several years [68], [69]. These labels allow for active ID transmission, rewritable memory as well as an increased storage capacities up to 1 MB.

6.1.2. Why allied industries adopted track and trace

Now that we have explored the origins and capabilities of T&T technology from a supply chain perspective, we can have look at the impact that the technology has had on allied industries. When thinking about quality control using T&T, an important example can be found in the food industry. Over the years, the coding and tracking of food “from farm to fork” has become increasingly important [60], [70]. In the light of multiple food quality crises like the outbreak of Bovine Spongiform Encephalopathy (BSE), the dioxin scandal or more recently the contamination of free range eggs with fipronil, food safety has become a hot topic in public debate. Here traceability allows food producers and governing entities to control food quality and retrace quality deviations back to its origins to help mitigate and prevent such crises.

Closer to home, financial losses combined with legislative efforts compelled the pharmaceutical industry to implement standardized drug barcoding and T&T to limit drug counterfeiting and trafficking [62], [71]. Extrapolating from the experiences of the introduction of barcodes in the retail industry in the 1970s, pharmacological companies projected additional benefits. It was hypothesized that label standardization would also lead to a decrease in stock assets and stock expiration, result in more efficient stock handling, and would improve drug use and drug compliance [62].

Under promotion of the International Medical Device Regulators Forum, the US recently introduced similar legislation for medical equipment as well [72], [73], which is expected to be implemented in the EU within the next couple of years [74], [75]. As of 2013 all medical instruments used in the US must be provided with a Unified Device Identifier (UDI) which will be registered in a Global Unique Device Identification Database (GUDID) for quality monitoring purposes [73]. These UDI codes should be readable for men but can be supplemented by machine based read-out in terms of barcodes or RFID [75]. In line with the aforementioned case of pharmaceuticals, similar benefits are predicted [62].

Over the last years RFID technology has found its way to an increasing amount of hospitals as well. Over the course of several pilot studies, various hospitals investigated the applicability of RFID in settings varying from patient monitoring and walking route logging, to the tracking and tracing of large equipment and pharmaceuticals [76]. The benefits of these T&T systems were found to include; increased patient safety, improved medical services, improved patient satisfaction, improved business processes and workflow, decreased equipment costs, improved inventory management and decreased overall operational costs resulting in a high overall return on investment.

In addition to the aforementioned substantial benefits of standardized labeling, we project that a combined implementation with a suitable T&T system can have an even more profound impact. Logging instrument tray location and contents would, for example, provide detailed insights on instrument usage, sterilization frequency, equipment breakdown frequency, corresponding instrument downtime and instrument whereabouts. This information can in turn be used by healthcare managers and medical experts to support sound and responsible decision making. Based on the aforementioned information, for example, hospitals can adjust capacity dimensions, work flows and surgery order protocols and instrument tray composition to perform more efficient procedures while limiting instrument wear and tear. The incorporation of UDI legislation and the accompanying technologies should therefore be an important part of the investigation conducted in this chapter.

6.2. Addressing the pitfalls of the current IT system

Now that we have established a principle understanding of T&T technologies and their potential impact, let us look at how we can apply T&T to address the pitfalls of the current IT environment. Provided that the OLVG is willing to use the forecasting model as introduced in chapter 5, we can identify multiple important caveats in the current IT environment that need to be addressed in order to facilitate its implementation. In this section we investigate which caveats we consider most pressing and we elaborate on how these issues should be tackled by formulating an information management strategy.

In sections 4.1 and 4.2 we described Lead time (LT) and quality related performance measures by which Lean based supply chain control should be enforced. In section 4.3, however, we found that none of these performance measures are recorded or used to govern the instrument sterilization cycle. As described in the previous section, the continued measurement of these performance indicators can provide a powerful tool for continuous quality monitoring. Moreover, in chapter 5 we found that these indicators are crucial for establishing a production planning, based on demand forecasting.

In order to couple instrument quality to process quality, the IT environment at OLVG must be able to record both the single tray throughput and single tray quality on specific locations. If we want to redesign the IT environment to accommodate this we will have to address the question of which IT system is required to execute this task. Over the course of this thesis we found that the instrument sterilization cycle is mainly controlled by three of the IT systems used by OLVG, being the EPF system, the OR tracing system and the

CSSD T&T system (figure 14; top). Of these systems the EPF is used to document all patient related information like patient symptoms, diagnosis, treatment schedules and surgery schedules [23]. If a patient is selected to undergo surgery, the EPF system is then used to prompt a demand for instrument trays by forwarding a surgery order protocols to the SD main storage. We can therefore say that even though the EPF is used to generate throughput in the sterilization cycle, it is clear that it is a secondary function compared to its intended use.

Following this analogy we can conclude that the remaining two tracing systems should be responsible to provide full T&T coverage over the sterilization cycle. Unfortunately we have observed that the use of these systems is relatively fragmented and focused on supporting single departments only. As a result of this phenomenon, we found in section 4.3 that the OLVG does not maintain a coherent quality registration system which spans the entire sterilization cycle. Furthermore, we found in section 4.4 that these two systems can only be used to monitor instrument tray throughput to a limited extent. Apart from the poor data quality, especially the recorded throughput of the OR tracing system seemed to be at risk due to inadequate utilization of the registration system in the OR. For the CSSD T&T system, on the other hand, we observed that the recorded throughput sometimes exceeded the demand that was prompted by the EPF. Because we believe that the fragmentation of the IT systems plays an undeniable role in permitting these issues, we opine that the OLVG should consider using a singular and fully standardized IT system to mitigate these issues.

What we propose to do is best summarized by figure 14 (bottom). In this figure we can see that the OR Tracing system and CSSD T&T will be merged into an OR Track and Trace system in order to address the IT fragmentation which hinders the data registration. This system will be utilized to document most the performance indicators formulated in chapter 4. Furthermore, this merged system will facilitate additional tasks which were previously dispersed over the OR Tracing and CSSD T&T systems. What we can additionally see is that the OLVG EPF system is not included in the merged system because we believe that it should remain a standalone system with patient centered core functions.

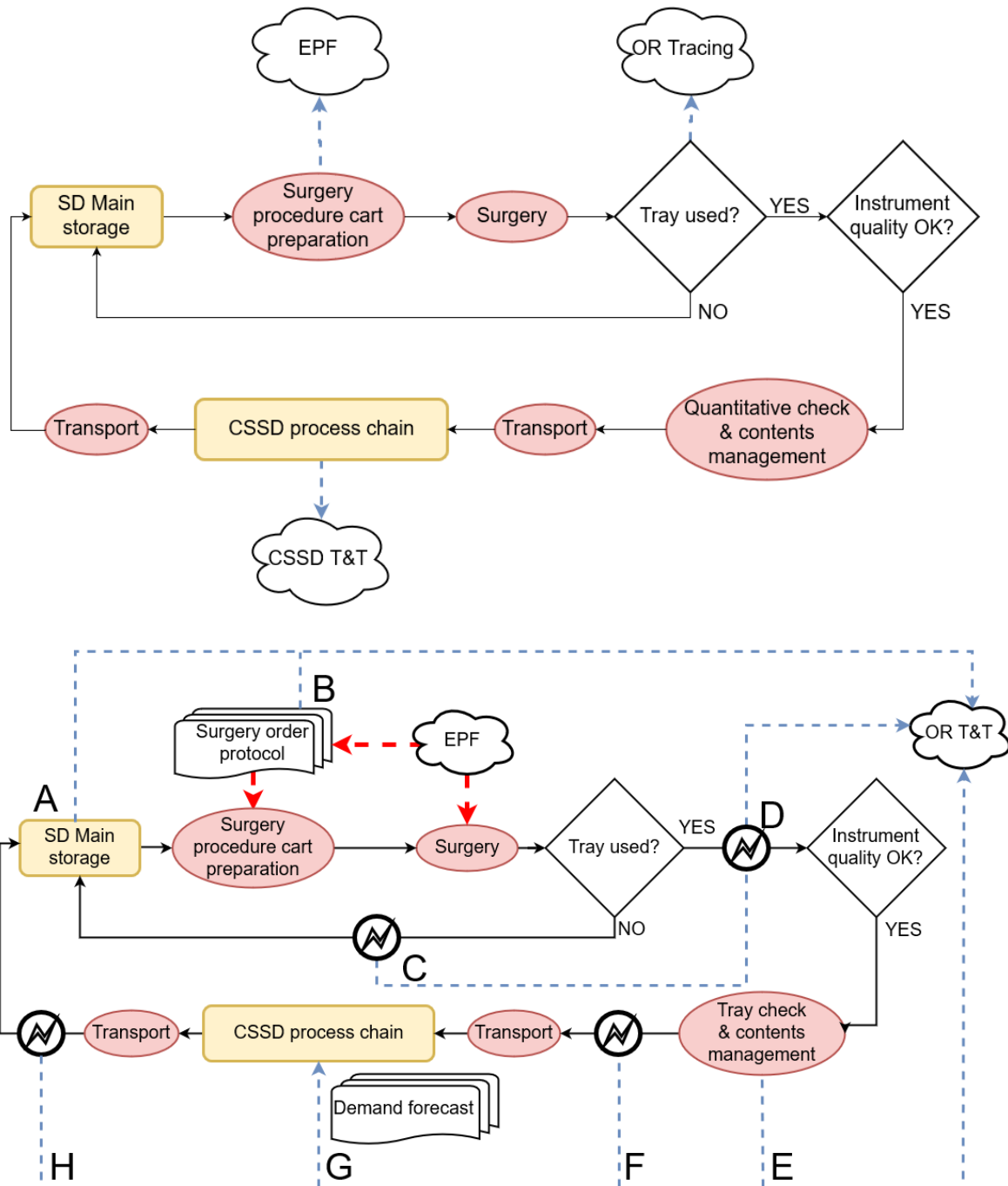


Figure 14. This figure depicts the ground form of the current sterilization cycle. Here the top ground form includes the current IT environment. The bottom ground form, on the other hand, displays a redesign of the IT environment which encompasses the information management strategy formulated in this section.

To get a more detailed view of which information is recorded at which location we included table 13. Here table 13 tells us that the throughput of the sterilization chain is measured at various scanning points throughout the entire cycle (points C, D, F, H). In addition to these throughput scanning points we also chose to include the tray demand prompt by documenting which trays are ordered according to the surgery order protocols (B). These throughput points will not only be used for forecasting as proposed in

chapter 5 but should also be used to facilitate a throughput data feedback system. This feedback system should enable medical staff and hospital management to detect if the throughput is registered coherently through the system. This is especially relevant through the points of B, C and D where the throughput in D should equal B minus C.

Furthermore, we have selected four main critical control points of instrument tray quality in the sterilization cycle, being points A, C, D E. This was done in a fashion comparable to Hazard Analysis and Critical Control Points methodology which is utilized for food quality registration systems [77]. Here point A was chosen as a check point for instrument tray sterility both in terms of compromised wrapping and sterility expiry. This was done because we assumed that the patient health risk resulting from non-sterile equipment would be highest for equipment which is obtained from the storage prior to surgery.

Points D and E, on the other hand, were selected as control points for instrument quality in terms of instrument functionality and tray composition. This choice was made because we assumed that most functionality and composition related defects will come to light as soon as the instrument trays are opened and used. Last, if the new system registers the throughput of the return flow at point C, and also documents why these trays have remain unused during surgery, the OLVG will be able to determine whether the surgery order protocols are up to date.

Table 13. An overview of which information is collected at which location in the sterilization cycle.

Label	Location in supply chain	Description of collected information
A	SD main storage	<ol style="list-style-type: none"> 1) Registration for instrument expiry 2) Registration of instrument tray stock positions 3) Registration of tray sterility deficiencies (e.g. ruptured tray wrapping)
B	Order protocol	<ol style="list-style-type: none"> 1) Registration of instrument tray demand in order to compare with the trays that are return unused
C	Post-surgery	<ol style="list-style-type: none"> 1) Registration of unused equipment including reason for return (wrong tray or simply redundant for current procedure)
D	Post-surgery	<ol style="list-style-type: none"> 1) Registration of equipment forwarded for sterilization including reason (damaged packaging prior to usage, wrong tray composition or simply utilized during current procedure) 2) Throughput analysis, D should equal B-C 3) Registration of used equipment for patient recall purposes
E	Instrument quality check	<ol style="list-style-type: none"> 1) Registration of tray contents adjustments
F	Pre-sterilization at CSSD	<ol style="list-style-type: none"> 1) Registration of incoming trays for sterilization
G	Sterilization (CSSD process chain)	<ol style="list-style-type: none"> 1) Registration of CSSD process information, CSSD Track and Trace 2) Providing process input by means of demand forecast
H	Post-sterilization	<ol style="list-style-type: none"> 1) Registration of sterilization process output 2) Comparing realized output to planning to determine the fill rate

6.3. Track and trace selection considerations

Now that we know what our information management strategy looks like and know where we want to measure our information we can have a look at the hardware that we want to use to implement the strategy. In section 6.1 we explained what Track and Trace (T&T) is and which technologies enabled its implementation. In section 6.3.1 we briefly discuss the pros and cons of the two most important T&T modalities in order to make a selection for our T&T system. In section 6.3.2 we continue this discussion by focusing on the costs and benefits aspects related to the implementation of the modalities.

6.3.1. Weighing the pros and cons in the selection of a T&T modality

In this section we will have a look at the upsides and downsides of the two most important T&T modalities for our supply chain, 2D-barcodes and RFID. In a 2012 article Bansal et al. compared the most important technological features of both modalities, which we have summarized in table 14 [78]. From this table it can be deduced that use of barcodes comes with several obvious advantages. Because of the maturity of the technology its implementation is supported with a well-developed eco-system. Furthermore, the simplicity of barcoding means that the technology can be implemented at relatively low costs.

The utilization of barcodes, however, also comes with distinct disadvantages which are inherent to the nature of the technology. First of all barcode labels require a clear line of sight in order to target the label with a read-out device [79]. Second of all barcode scanning is ill suited for bulk scanning because items can only be scanned in series. Third, despite the drastic increase of data density with the introduction of 2D-barcodes a further increase in data density is complicated by the size of the 2D-barcode, the printing resolution of label printers and the closely related resolving resolution of scanners [65]. A last downside of printed labels would be that the data stored on the label is not updateable opposed to other interactive technologies [68].

Table 14. Comparison of the technical features of 2D-Barcodes and RFID [78]

Technological features	2D-Barcode	RFID
Direct line of sight requirement	Yes	No
Difficult to duplicate or alter	No	Yes
Readability interference with liquids/metals	No	Yes
Cost of tags	Low	High
Tag data storage	Low	High
Bulk tag reading	No	Yes
Initial technology set up cost	Low	High
Eco-system and/or standards maturity	High	Medium
Tag feature's extendibility (e.g. Tag with sensors)	Low	High

Adopting RFID instead of barcodes, turns the barcode negatives into RFID positives. Here RFID is eminently suited for bulk scanning, whilst not requiring a clear line of sight [78]. Furthermore, we already highlighted in section 6.1.1 that new RFID label standards allow for active data transmission, rewritable memory and increased data storage capacities [68].

Of course the use of this technology comes at the cost of other specific drawbacks. Two important examples mentioned in table 14 are the fact that the radio technology is sensitive to read-out errors due to material interference and that the technology is relatively expensive when compared to printed

barcodes [78]. Next to these general drawbacks RFID also has a couple of downsides which are specific to the adoption for surgical instruments. Here the first downside is the fact that the labels are currently too large to be attached to small objects. Here the tag size is mainly influenced by the size of the RF antenna which is incorporated in the tag [69], [80]. When trying to ensure proper read-out at larger distances, downscaling the antenna can prove detrimental. In addition, it will prove difficult to attach RFID labels to existing instruments. Physically attaching large RFID tags to instruments will alter their overall size, shape and functionality. These updated instruments will therefore require recertification (CE-certification) to make sure that they are in compliance with existing regulation and are safe to use in a clinical setting [81].

The last downside to take into account with RFID tags is read-out security [69]. Read-out on distance is inherent to the nature of this technology. When comparing RFID read-out distances over various standards we found that they can vary between 3m and 100m respectively [82]. This also means that malicious third party entities are able to read-out, manipulate or destroy potentially sensitive information from other rooms or in some cases even from outside. When implementing RFID, the stakeholders should therefore be aware of these security issues and provide protection accordingly.

When we put this information in perspective relative to the OLVG case we deem the use of RFID for the tracking of single instruments not feasible. Surgical instruments will therefore have to be followed by the use of UDI compliant (2D) barcodes. For T&T on instrument trays, on the other hand, the OLVG does have a choice between 2D-barcodes and RFID. As demonstrated in this section, RFID implementation has a lot benefits over barcode implementation with the caveat that this technology comes with a larger price tag. In the next section we will therefore try to quantify this difference in case of OLVG East.

6.3.2. Reviewing the costs and benefit considerations

In the previous section we discovered that OLVG East still has a choice whether to use 2D-barcodes or RFID to track and trace instrument trays. The major decision factor in this choice is the price difference between the two modalities. In this section we therefore evaluate these cost differences with respect to the projected benefits in order to facilitate decision making. When we look at the literature on RFID and UDI barcoding, several studies provide a clear cut insight on the cost implications for hospital based implementation [62], [76], [83], [84]. In order to come to a comprehensive cost overview the assumptions of these studies will be applied to our case. Let us first look at the implementation of UDI compliant barcodes.

In our observations of the surgery department we noted that OLVG East has 12 ORs and at least four storage locations which should be equipped with scanning equipment. Furthermore, we know that all of the trays are already provided with barcodes and RFID tags which are utilized in the CSSD T&T environment.

In order to implement UDI compliant barcoding the following assumptions are commonly made:

- For the OR, robust scanning stations have to be installed which also operate under conditions of low light intensity. Such scanners are estimated to cost 2,000 euros and are written-off in five years [62], [84].
- On storage locations it is assumed that at least 2 handheld scanners need to be available. These scanners are estimated to cost between 300 and 600 euros. For our investigation we have chosen to use a price indication of 450 euros per scanner which is also written-off in five years [62], [84].

- Licenses will have to be bought for a software package and a labeling standard. Cost estimates of software packages vary between 500 and 90,000 euros. Annual license fees for both software and barcode standards amount up to 12,500 euros on an annual basis. For our investigation we have chosen to use a software purchasing price of 50,000 euros [62], [84].
- Costs involved in the system implementation are estimated to be around 50,000 euros [84].
- Costs involved in the maintenance of IT systems are estimated to be around 100,000 euros on an annual basis [84].
- For the cost analysis we lastly assumed that staff training for both RFID and UDI barcoding would be comparable. Estimates regarding staff training amount to 50,000 euros [76], [84].
- The replacement costs of UDI barcodes are negligible.

These assumptions can be summarized into a cost overview (table 15).

Table 15. Cost overview of the implementation of UDI barcoding at OLVG East

Cost item	Single purchasing costs	Annual costs
Scanning equipment	€ 27,600	€ 5,520
Software and licensing	€ 50,000	€ 12,500
System implementation	€ 50,000	€ -
IT maintenance	€ -	€ 100,000
Staff training	€ 50,000	€ -
Totals	€ 177,600	€ 118,020

Let us now shift our attention to the costs involved in the implementation of RFID. For RFID the following assumptions can be made:

- For the OR, handheld scanners will have to be utilized in order to enhance scanner targeting and minimize scanning errors. Such scanners are estimated to cost 5,000 euros and are written-off in five years [76], [84].
- On storage locations it is assumed stationary scanning portals need to be installed. The amount depends on the amount of entries to the storage rooms. Here it was assumed that the SD Main storage as 2 entrances and that the other storage locations only have 1 point of entry. These stationary scanning portals consist of 2 scanners which are each estimated to cost between 1,500 and 2,000 euros. For our investigation we have chosen to use a price indication of 1,750 euros which is written-off in five years [76], [84].
- Licenses will have to be bought for a software package. Cost estimates of software packages vary between 500 and 90,000 euros. Annual license fees amount up to 7,500 euros on an annual basis. For our investigation we have chosen to use a purchasing price of 50,000 euros [76], [84].
- Costs involved in the system implementation are estimated to be around 50,000 euros [84].
- Costs involved in the maintenance of IT systems are estimated to be around 100,000 euros on an annual basis [76], [84].
- For the cost analysis we lastly assumed that staff training for both RFID and UDI barcoding would be comparable. Estimates regarding staff training amount to 50,000 euros [84].
- The replacement costs for RFID tags are estimated to be between 0.10 and 1.00 euros for passive tags and between 1.00 and 50.00 euros for active tags [76].

These assumptions were summarized into a cost overview as well (table 16).

Table 16. Cost overview of the implementation of RFID at OLVG East

Cost item	Single purchasing costs	Annual costs
Scanning equipment	€ 77,500	€ 15,500
Software and licensing	€ 50,000	€ 7,500
System implementation	€ 50,000	€ -
IT maintenance	€ -	€ 100,000
Staff training	€ 50,000	€ -
Totals	€ 227,500	€ 123,000

When we look at the projected financial benefits of these standardized labelling methods the literature unfortunately provides less clear cut answers. According to the 2012 McKinsey business case a annual benefit varying between 0.9% to 1.4% of the annual revenue can be expected [62]. When applying this to the 2016 management report of the OLVG this would amount to annual savings ranging from 4.62 to 7.18 million euros over the entire hospital conglomerate. Assuming that the revenue is equally distributed over OLVG locations East and West these numbers are 2.31 and 3.59 million respectively. Here the McKinsey report, however, looks at the benefits of implementing standardized labeling over both medical equipment and pharmaceuticals [62]. This means that in practice these values are likely to be lower when we only apply standardized labeling to instrument trays. A more realistic estimation of the benefits can be given based on a 2011 GS1 business case report for the implementation of UDI on medical instruments [83], [84]. According to this business case the savings for OLVG East are likely to range from 768 thousand to 1.22 million euros on an annual basis [83].

To summarize the findings in this section we have included table 17. Here what we can see is that the implementation of RFID is relatively more expensive than the implementation of UDI. The cost differences, however, are marginal when we compare them to the projected benefits. Here the price gap is of course reduced by the fact that both barcode labels and RFID tags are already present on the current instrument trays. Follow up research has to investigate if the current labels can be seamlessly integrated into a new software platform. To give a complete overview we have therefore also included the replacement costs of single barcodes and single RFID tags. Here we also have to keep in mind that especially active RFID tags need to be changed every other year because of the limited battery lifetime of the tag.

Table 17. Overview of the cost indication for UDI barcodes versus RFID

Expected costs UDI Barcodes	Single purchasing	Annual
Replacement costs barcodes		Negligible
Implementation costs UDI barcodes	€ 177,600	€ 118,020

Expected costs RFID	Single purchasing	Annual
Replacement costs passive RFID tags		€ 0.10 – € 1.00
Replacement costs active RFID tags		€ 1.00 – € 50.00
Implementation costs RFID	€ 227,500	€ 123,000

Expected benefits standardized labelling		€ 768,000 – € 1,224,000
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6.4. Discussion

When we look at the previous chapters we found that sterilization cycle at OLVG had a hampered control mechanism. This problem arose because the materials management strategy was poorly translated into performance standards by which the work processes should be governed. In turn resulted in the fact that the work process are conducted without a process planning. In order to restore this mechanism, we proposed to stimulate the process planning by creating a stochastic forecast of instrument throughput based on past surgery demand and patient centered performance measures.

This planning issue is exacerbated by the fact that the OLVG currently does not use an overarching information management strategy. As a result we found in chapter 4 that the OLVG does not maintain a coherent quality registration system which spans the entire sterilization cycle. Moreover, we found that the current IT environment cannot be used to measure any performance indicators other than instrument tray throughput. For this reason we typified the IT environment as highly fragmented and centered to serve single departments. We therefore questioned whether solely implementing a process planning would be enough to restore the planning function, or if this should be accompanied by a redesign of the IT environment.

In this chapter we reflected on what this redesign should look like. In section 6.2 we proposed to merge the OR Tracing and CSSD T&T system to form a single IT system that covers all the activities in the sterilization cycle (figure 14; bottom). The OLVG EPF system on the other hand is not included in the merged system because we believe that it should remain a standalone system with patient centered core functions. Here we can even debate whether the issuing of a surgery order protocol should even be done by the EPF system or if it should relay its surgery orders through the new OR T&T system. This line of thought would also resonate with the view of centralized versus decentralized management which we explained in section 5.4.2. Here we stated that management should be centralized where it is necessary and decentralized where it is possible, in order to generate the highest value from a care perspective [57].

In section 6.3.1 we reviewed the pros and cons of the two possible hardware modalities to implement the redesign of the IT environment. Here we found that the technological characteristics mostly favor the use of RFID over the use of UDI compliant barcoding. The most important benefits were found to include that RFID allows for more efficient tag reading and that this standard does not required a clear line of sight for scanning. An important downside of the implementation of RFID is that it is more expensive than the use of barcodes. To investigate whether the additional costs would be word the investment we chose to compare the implementation costs versus the projected benefits in section 6.3.2. Here we found that the implementation of RFID is indeed more expensive compared to UDI compliant barcodes, but that this cost difference is amply covered by the expected benefits. Unfortunately we did find ourselves unable to differentiate between the benefits of implementing UDI barcodes versus implementing RFID based on the obtained literature. Here we estimate that the operational benefits of the implementation of RFID will be higher because it can potentially save large amounts of time through its improved scanning capabilities. This aspect should therefore be quantified in additional research.

If we look at the results of section 6.3 in general we deem it most likely that OLVG East will adopt RFID to provide T&T functionality for their instrument trays. Single instruments, on the other hand, will have to be traced by UDI compliant 2D-barcodes, because the RFID technology is not ready to be implemented on small sized objects and cannot be attached to existing instruments. In such a system we expect that it will

be possible to register the 2D-barcodes to the RFID tag of the instrument trays to account for Track and Traceability of single instruments through the sterilization chain.

At this point the information management strategy formulated in this chapter is strictly aimed at addressing the issues that we found for instrument tray sterilization. If we revisit the overall flowchart in figure 2 (chapter 3), however, we can basically discern a second supply chain as well, which is inextricably connected to the sterilization cycle. Here this second chain can be seen as a servicing chain to the sterilization cycle because it provides (new) functional equipment for the instrument trays if the old equipment has broken down. Despite the fact that we have determined that the issues of this cycle fall outside the scope of this thesis, we would nonetheless like to offer a potential perspective on this second supply chain (figure 15).

As established in chapter 3 we found that most of the instrument administration in relation to the spare instrument supply chain is done by hand. In section 3.2.1, for example, we found that spare instruments are ordered manually in the ERP when the stores have been depleted. Since this ordering process is conducted at the insights of the employees involved, this means that ordering intervals as well as order sizes are arbitrary. We would therefore like to recommend that future research looks into whether this process can be automated by utilizing minimum and maximum stock reference levels. Here the stock levels should be determined in such a way that they also include the amount of instruments that are present in the instrument trays.

Additionally we discovered in section 3.2.2 that the instrument repair department (IRD) makes use of an IRD Tracing system. This tracing system is used to document repair details, supplier contacts, repair related expenses and repair frequency for a select variety of instruments. We would therefore like to recommend that future research should focus on whether or not this tracing system can be expanded to include all instruments in the sterilization cycle.

The last point that we would like to raise regarding the spare instrument supply chain, is that both the ERP and IRD Tracing IT systems cover a similar focus area. What we mean by this is that both registration systems are used to organize the replenishment of spare instruments. In analogy to the merger of the OR Tracing and CSSD T&T systems we would therefore like to propose that a merger between the IRD Tracing and ERP is investigated as well.

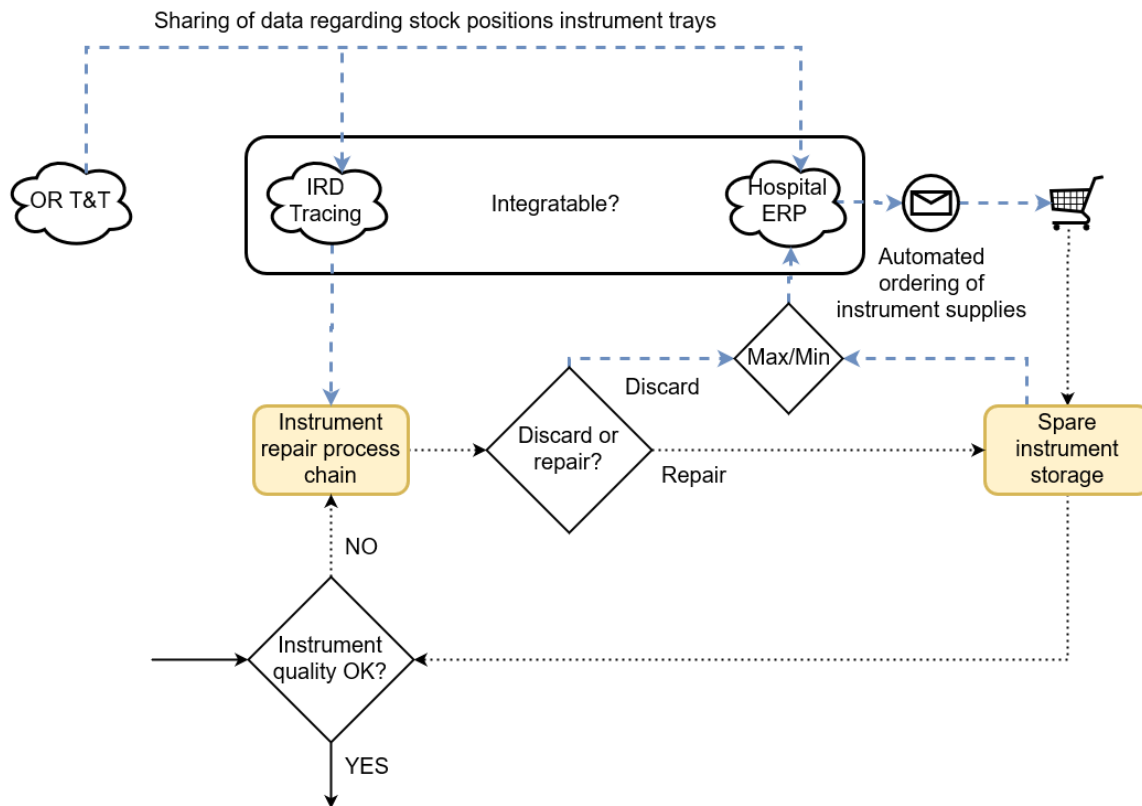


Figure 15. This figure depicts the ground form of spare instrument supply chain. For this ground form a number of issues are raised which should be looked into in future research.

6.5. Conclusion

In chapter 4 we concluded that the implementation of a process planning should be accompanied by the introduction of a redesigned IT environment. In this chapter we addressed this topic by formulating an information management strategy in section 6.2. In short, we described that this environment should consist out of two systems which each cover a distinct part of the instrument sterilization cycle. Here an OR T&T system should cover all the tasks, and record all the data related to the management of instrument tray stocks. A separate EPF system, on the other hand, should be used to monitor all patient related tasks.

In section 6.3 we investigated which T&T modality would be most suited to facilitate the implementation of such a system. After weighing all the advantages and disadvantages we reached the conclusion that separate instruments should be traced by the use of UDI complaint 2D barcodes whilst instrument trays can be traced by using RFID.

In chapter 4 we determined that the spare instrument replenishment supply chain falls outside the scope of this thesis. Because of our limited knowledge regarding this supply chain, we chose to provide a couple of suggestions which could be addressed in future research.

7. Summarizing the conclusions and recommendations

Over the course of this thesis we reviewed the logistical processes which are involved in instrument sterilization cycle of the OLVG hospital in Amsterdam. The current hospital is a merged organization which comprises the former Sint Lucas Andreas hospital, located in Amsterdam west, and the former Onze-Lieve-Vrouwen-Gasthuis, located in Amsterdam east. This merger has currently entered its final phase in which departments, processes and (financial) resources are merged, adjusted and standardized.

During our investigation, we found that this instrument sterilization cycle can be viewed as a circular supply chain in which instrument trays are stored, used, checked and cleaned, to be used again in the following repetition of the cycle. Here the flow of the instrument trays passes through three of the OLVG care supporting departments, being the surgery department (SD), the central sterilization service department (CSSD) and the instrument repair department (IRD). At present, this flow is still being organized separately over the two locations of the OLVG. To investigate the potential of merging the process chains over the two hospitals, the SD of OLVG East was interested to learn more about the potential for process improvements in the sterilization chain in general. The SD therefore formulated a problem description which broadly covered process improvements to reduce the amount of tray sterilizations in the short term (1), process improvements to reduce the amount of trays in the long term (2) and process improvements to enhance quality monitoring through track and trace (3).

In relation to these formulated problems the SD hypothesized that the main challenge in solving these issues would be to obtain coherent performance related evidence from a highly fragmented IT environment. To cope with the inherent challenges posed by the problem description, we chose to formulate a more generalized research question:

“What do the work processes of the instrument logistics cycle entail and what opportunities are there to optimize these processes to impact instrument storage, usage and maintenance?”

The central research question was subsequently broken down into two distinct parts for a problem solution process. Here the first part of the question was aimed at describing the current state of in the instrument supply chain (chapter 2 section 1), while the second part tries to establish a future image of the sterilization cycle (chapter 2 section 2). This problem solving process was subsequently divided over a number of chapters which all include their own discussion and conclusion sections.

To provide a comprehensive overview of the entire thesis we chose to summarize the chapters by utilizing the sub research questions as outlined in chapter 2. Here section 7.1 addresses the current state of in the instrument supply chain, while section 7.2 looks at the future image of the sterilization cycle. In section 7.3 we provide an answer to the main research question and put this answer in perspective using the original problem description of the SD. Furthermore, this section will highlight the limitations of this research in order to offer a potential course for future research.

7.1. The current state of the system

To examine the current state of the instrument sterilization cycle we hypothesized that it is crucial to know a couple of things. First off we needed to know which processes are conducted by which department and we were interested to learn how these work processes are monitored. Second we needed to identify the bottlenecks that cause the issues which are encountered at OLVG in order to offer possible solutions. These subject matters were covered by sub-questions 1 and 2 in section 2.1. To describe the current state of the

sterilization cycle we therefore chose to answer sub-question 1 in section 7.1.1 and sub-question 2 in section 7.1.2

7.1.1. Describing the instrument sterilization cycle

In this section we answer sub-question 1 as formulated in section 2.1:

1) *What work processes does the overall instrument supply chain entail and how are these processes monitored from a holistic perspective?*

- a) Which work processes are conducted by which of OLVG RVEs and who are the employee stakeholders involved?*
- b) By what means is the performance of the sterilization cycle monitored in order to manage the overall work flow?*
- c) How do the issues, explained by the SD in section 1.2, manifest themselves in practice?*

This question was answered in chapter 3. In section 3.2 we outlined the basic layout or “ground form” of the instrument sterilization cycle which can be observed in figure 2. The description of the work processes in this cyclic supply chain are summarized in table 2. Next to the separate process steps, this table also lists the respective employee stakeholders per work process and describes which of the five IT support systems is involved in conducting each of the process steps.

To give a basic idea of what the process chain entails we can describe it as follows. Instrument trays are metal baskets which contain a predetermined selection of medical instruments. All the instrument trays that can be used for a surgery are stored in the SD main storage. From the SD main storage, instrument trays are loaded on to surgery procedure carts together with disposable instruments according to a surgery order protocol which is specific for each procedure. In most cases these trays will be used during surgery after which they will undergo a quantity and quality check. During these checks it will be determined which instruments can enter the sterilization cycle directly and which instruments require repairs. Unused instrument trays are returned to the SD main storage.

Except for instrument repairs and instrument sterilization all the aforementioned steps fall within the SD sphere of influence. For OLVG East sterilization is carried out by Clinium, which is an external CSSD company located in the greater Amsterdam municipality area. Faulty instruments on the other hand are repaired by the IRD or are replaced by the SD. The consideration of repair versus replacement is done based on the nature of the defect, the estimated cost of repair and the estimated cost of instrument replacement.

After reviewing the sterilization cycle it became apparent that the OLVG has great difficulty storing and managing the large amounts of instrument supplies required for the surgeries. On a first glance, we were not able to determine if this is simply caused by a lack of space, or if this is due to overstocking. Furthermore, we discovered that the compilation of surgery procedure carts is subjected to high degree of variability originating from the surgery schedules.

7.1.2. Pin-pointing the bottlenecks

In this section we answer sub-question 2 as formulated in section 2.1:

2) *What are the bottlenecks in the current instrument sterilization cycle from a fundamental design perspective and how should they be resolved?*

- a) How should supply chain control be organized from a theoretical and Lean based perspective?*
- b) Which performance indicators should be used in organizing such a supply chain?*
- c) To what extent is the organization of the current sterilization cycle in agreement with theoretical gold standard?*
- d) In what way should we alter the current sterilization cycle in order to create a more reliable and predictable flow of instruments?*

This question was answered in chapter 4. From literature we could deduce that supply chains managers can be faced with two types of problems when organizing supply chains; design problems and control problems. Here design problems refer to the organization of the core processes that are involved in the logistical chain. Changes that are made in answer to design problems are therefore reflected by alterations in the basic layout of the work processes. Control problems on the other hand, refer to how the current work processes are managed without affecting the basic layout. Changes made with regard to control problems usually involve measures like altered process planning and improved process alignment. For this thesis we have chosen to approach the issues at OLVG from a supply chain control perspective.

Based on the problem description in chapter 1 we hypothesized in section 2.1 that it would be crucial to ensure a stable flow of instrument trays through the sterilization cycle. In section 3.2 we saw this supposition strengthened by the fact that the availability of sterile instrument trays is directly reliant on a fast and efficient handling of used instrument trays. In order to do so we deemed the Lean methodology best suited to use as a platform strategy to ensure logistical control.

In sections 4.1 and 4.2 we described how supply chain control should be organized from a Lean perspective (figure 3). In short, the operational goals and performance parameters should be defined in a logistical policy which is consistently enforced over the entire supply chain. These goals and parameters serve as an input for the production planning which governs the future execution of the supply chain processes. During the execution of the work processes all sub-departments and employees make their individual decisions on how to fulfil or deviate from the planned production. After execution of the work processes the output of the processes is compared to the original planning to detect deviations from the goals based on the performance parameters which were framed in the production planning. If deviations occur, either the production planning or the execution of the work processes can be adjusted.

Furthermore, we formulated patient centered performance measures by which Lean based control should be enforced. According to our research these performance indicators should at least include the following:

- 1) The process lead time (LT) which can be defined as the amount of time between the initial order of a product and the moment of delivery.
- 2) The order fill rate (%FR) which is defined as the percentage to which an order is completed at the moment of delivery.
- 3) The process error rate (ER) which is defined as a measure of process quality by looking at how often a process step is conducted incorrectly at the first attempt. Because the definition of the

concept of quality is reliant, however, on the work process to which it is applied, we had to specify the separate error rates for each work process.

In section 4.3, however, we found that these performance measures are not measured nor used in practice. Additionally, we found that the work processes in the sterilization cycle are conducted as a mostly non-planned process chain in which sterilization takes place according to an “as soon as possible” principle. As the sterilization cycle is lacking its crucial planning functions (figure 8), the overall control mechanism can therefore be typified as highly reactive and primed on short term operational solutions.

In section 4.5 we discovered that this can prove detrimental for proper stock maintenance in the instrument sterilization cycle. As we classified the sterilization cycle as a make to stock (MTS) supply chain we discovered that the demand push/pull point is located relatively far downstream in the supply chain. As a result most processes are reliant on a well-structured planning based production push rather than a customer based demand pull. To remedy this we proposed to develop a demand forecasting model in order to give an estimate of how much instrument trays would be required to cover demand. This model should strictly focus on a demand forecast for reusable instrument trays in the instrument sterilization cycle and will disregard the forecast of spare instruments.

Next to the lack of a central planning, we have discovered that the IT systems that are currently in place are of limited use for measuring supply chain performance and thus enforcing a materials planning. This is caused by the fact that the IT environment is highly fragmented because a coherent information management strategy is currently lacking. To formulate an information management strategy, however, we will first have to look at how the proposed planning takes shape. In addition we have found that especially the instrument tracing system over the OR is not used adequately by the employee stakeholders.

7.2. An image of the future system

To generate an image of the future state of the instrument sterilization cycle we addressed the main flow disturbing factors that were observed in answer to sub-question 2. In chapter 4 we discovered that instrument flow is sub-optimal due to the lack of a process planning. We therefore proposed to develop a demand forecasting model in order to give an estimate of how much instrument trays would be required to cover demand. Furthermore, we found that the IT environment currently in place, is of limited use for measuring supply chain performance and thus enforcing a materials planning. This is caused by the fact that the IT environment is highly fragmented because a coherent information management strategy is currently lacking.

In this thesis we offered solutions to these issues by utilizing sub-questions 3 and 4 formulated in section 2.2. To describe the future state of the sterilization cycle we therefore chose to answer sub-question 3 in section 7.2.1 and sub-question 4 in section 7.2.2.

7.2.1. Implementing a stochastic demand forecast

In this section we answer sub-question 3 as formulated in section 2.2:

3) In the context of the urology department and in a general context, how can demand forecasting be utilized in order to reduce the amount of inventory?

- a) *How does demand forecasting impact the flow of goods and information relative to the “ground form” established in answer to sub-question 1?*
- b) *Which forecasting method should we use and how should a forecasting model be build?*
- c) *How can surgery order protocol and instrument tray compilation be impacted by the implementation of demand forecasting?*

This question was answered in chapter 5. In chapter 4 we emphasized the necessity to radically improve the planning functions of the instrument sterilization cycle by implementing a forecasting model to predict future instrument tray demand. In section 5.1 we proposed to build a proof of principle model in which the demand for specific procedures is coupled to the demand for the corresponding instrument trays. Utilizing this model we hoped to be able to give a correct estimation of the instrument tray supplies required to cover 97.5% of all possible instrument tray demand. Furthermore, we wanted to use the model to give a generalized idea of how surgery order protocol compilation should be adjusted in order to influence the amount of instrument tray supplies and instrument tray demand. In order to achieve these goals, we argued that the use of a stochastic forecasting model would offer the most appropriate starting point because these models have an innate capacity to cope with data variability.

For the investigation in this thesis we chose to build the instrument tray demand forecasting model, based on the demand for 25 procedures out of the possible 93 procedures for the Urology department at OLVG. In section 5.2.1 we established that a Poisson probability distribution would offer the best fit for the selected procedure demand data. In section 5.2.2 we continued by explaining how the demand for procedures is translated in the demand for instrument trays. In the end we were able to generate a Poisson forecast for 29 different instrument tray types with an average demand varying between 0.1 and 8.9 trays per week.

After discussing the results of section 5.3 we were able to conclude that this forecasting model does not offer a valid representation of the actually recorded instrument tray demand for all instrument tray types. By utilizing the top 25 procedures we were able to predict a demand for 29 out of the 84 possible tray types. Using the forecasts for these 29 tray types we were able to cover 82.38% of all possible tray demand opposed to the intended 97.5%. If we shift our attention to the forecasting accuracy, we found that our forecasting model based on past procedure demand was just as accurate as a forecast based directly on past tray throughput. This conclusion was reached based on a mean absolute scaled error (MASE) analysis, where a MASE of 1 indicates an equal ratio between a forecast error and a reference error. For our MASE analysis values of 0.98 +/- 0.26 were observed for the 29 predicted tray types whereas the MASE values averaged 0.63 +/- 0.55 over all 84 different tray types.

In section 5.4.1 we found that it is possible to improve the stochastic forecasting model by including more procedures to the forecasting model. Given the vastness of the work involved, however, it remains to be determined whether it is worth the effort to expand this model in its current form. In section 5.4.3 we therefore offered that a different software platform could be used to automate demand forecasting as it was done in this thesis. Furthermore, we offered that an easier forecasting method could be generated

based directly on the instrument tray throughput data of the central sterilization services department (CSSD). This can only be done under the condition that the reliability of the CSSD data is verified.

What this model does offer is a way to look into order protocol composition. From the description of order protocols and instrument trays in section 3.1 one might argue that surgery order protocols provide a clear-cut directive for which tray subsets are to be used for a specific procedure. In practice, however, the relationship between a subset of trays and a procedure is not as unambiguous as one might hope. The uncertainty in this relationship can be reduced by looking to the procedure frequency versus tray request data as demonstrated in section 5.2. Here deviations in practice can be utilized to inform the medical staff which empowers them to make the right decisions for order protocol adjustment.

7.2.2. Formulating a new information management strategy

In this section we answer sub-question 4 as formulated in section 2.2:

4) Which IT improvements and which Track and Trace technologies need to be considered to cement the aforementioned demand forecast into the clinical practice?

- a) *What information is required to properly control the sterilization cycle and from which IT systems should this be obtained?*
- b) *Which Track and Trace technologies are suitable to be implemented to gather the data required by the IT monitoring systems?*
- c) *Which considerations need to be made in the selection and implementation of these Track and Trace technologies?*

This question was answered in chapter 6. In chapter 4 we concluded that the implementation of a demand forecast based process planning should be accompanied by the introduction of a redesigned IT environment which takes into account how the forecasting model works. In chapter 6 we addressed this topic by formulating an information management strategy. Due to the expressed interest of the OLVG into Track and Trace (T&T), this technology played a central role in the development of the strategy.

In section 6.1 we first explained what T&T is and barcoding technologies played an important role in its implementation. In addition we explained how the emerging RFID technology is starting to compete with these well-established standards. Last, we highlighted that T&T plays an important role in quality monitoring and that new legislation dictates that a unified standard for quality monitoring will become mandatory for organizations operating in the healthcare industry.

In section 6.2 we formulated what the information management strategy should look like guided by the forecasting model introduced in chapter 5. In short, we described that the OLVG should not only document the patient centered performance measures introduced in chapter 4, but should also measure procedure demand, instrument tray demand and instrument tray throughput to facilitate demand forecasting. To accommodate this, we hypothesized that it is crucial to address the fragmentation of the current IT systems which hampers error free information documentation.

If we look at figure 14 in chapter 6 we can see that we introduced an IT environment which should consist out of two systems, each covering a distinct part of the instrument sterilization cycle. Here an OR T&T system should cover all the tasks, and record all the data related to the management of instrument tray stocks. A separate EPF system, on the other hand, should be used to monitor all patient related tasks. In section 6.3 we discussed which T&T modality would be most suited to facilitate the implementation of such a IT environment. After weighing all the advantages, disadvantages and cost implications we reached

the conclusion that separate instruments should be traced by the use of UDI compliant 2D barcodes whilst instrument trays can be traced by using RFID.

7.3. Answering the central research question

Reviewing the answers to the sub- questions in sections 7.1 and 7.2 we can now answer the central research question:

“What do the work processes of the instrument logistics cycle entail and what opportunities are there to optimize these processes to impact instrument storage, usage and maintenance?”

In essence, the sterilization logistics cycle is a supply chain in which instrument trays move through various internal and external departments. Over the course of this chain we found that the trays are stored, used, checked and cleaned, to be used again in the following repetition of the cycle. The work process by which this is done are elaborately described in chapter 3. In this thesis we demonstrated that in such a complicated chain of processes, everything hinges on the control function which checks the delivered output to the desired output. Important in controlling these work processes is the establishment of common goals and the sharing of information throughout the supply chain to obtain the desired results.

In the case of the OLVG we found that this control function was impaired because both these conditions are not met to an adequate extent. To offer a solution to this problem we proposed to do two things. First we found that the OLVG should make use of a process planning. This can for example be established by forecasting future demand. Second we found that the IT environment needs a rigorous overhaul in order to promote adequate information sharing and utilization over the various departments.

7.3.1. Returning to the original problem description

In the introduction of this thesis we explained that the surgery department (SD) expressed a keen interest in the following question regarding the instrument sterilization cycle:

- 1) The SD wanted to know in which way the instrument tray supply chain should be improved in order to reduce the amount of instrument trays.
- 2) The SD was interested to learn which opportunities there were to support and improve quality control by implementing Track and Trace (T&T)
- 3) The SD wanted to know how instrument tray contents can be streamlined in short term, to achieve qualitative gains and to reduce the amount of instrument sterilizations.

If we put the answer to the central research question in perspective to the aforementioned topics we can briefly answer them as follows:

- 1) In order to reduce the amount of instrument trays in the long term we recommend that the OLVG makes use of mid to long term demand forecasts. In this way the hospital can establish how many trays need to be kept on storage to cover tray demand. If we look beyond the scope of this thesis the OLVG can also consider setting a deadline for surgery schedules so that the demand can be determined in an accurate fashion. This would in turn allow the CSSD department to generate a customer pull based flow in which trays are sterilized on demand. Such a setup would resonate even more profoundly with the aims of Lean, compared to the implementation of a demand forecast.
- 2) In chapter 6 we discovered that the use of T&T technologies can potentially have great benefits in terms of quality monitoring and process automation. Based on the advantages, disadvantages and

cost implications we reached the conclusion that separate instruments should be traced by the use of UDI compliant 2D barcodes whilst instrument trays can be traced by using RFID.

- 3) In order to streamline instrument tray contents, we recommend that instead of utilizing an imposed optimization and standardization we propose to formalize the decision making process that lies at the foundation of instrument tray and order protocol compilation. This can for example be achieved by creating (financial) restrictions and incentives, and by empowering staff members by providing a platform for informed debate. In this way the medical staff remains in the lead of operating in the patient best interests, whilst it creates an enhanced awareness of the organizational limits to do so.

7.3.2. Recommended action points for the OLVG

If we look back at the overall outcomes of this thesis a number of recommendations can be made for the OLVG. If we summarize these recommendations according to priority, the overview looks as follows:

- 1) The OLVG should at the least implement a demand forecast which allows the work process of the instrument sterilization cycle to be planned. To do so we recommend to utilize a Poisson based extrapolation of past demand data, in order to account for the variable and intermitted nature of the data. Other forecasting methodologies like moving average forecasting or normal demand forecasting have proven to achieve these goals insufficiently.
- 2) Implement a more coherent IT environment which at the least monitors the patient centered performance measures and instrument quality measures coherently throughout the sterilization cycle. This is not only relevant to get an accurate view of current level, location and quality of the instrument supplies, but can also be used to enhance the accuracy of the demand forecast.
- 3) The employee stakeholders of the work processes have to be trained in operating any IT system required for their job. Furthermore, they have to be made fully aware of the importance of correct instrument tray registration. In this way a lacking registration quality as observed in the OR tracing system can be avoided.
- 4) If both a demand forecast and a more integrated IT environment are implemented, make sure that this IT environment also documents measures vital to demand forecasting. Examples thereof are measures such as procedure demand and instrument tray demand.
- 5) Instrument trays and order protocols should be only be optimized and standardized with a clinical expert in the lead. In order to give direction to this streamlining process we propose to formalize the decision making process that lies at the foundation of instrument tray and order protocol compilation. Here a centralized management authority can influence the decision making process by imposing restrictions, creating incentives and empowering staff members.
- 6) Track and trace can be facilitated by utilizing RFID for the instrument trays. Separate instruments, however, have to be traced by barcodes because the RFID technology is not suitable to be used on smaller objects.

7.3.3. Recommendations for future research

Due to the constraints set for this thesis we recommend that the OLVG investigates a number of topics to a more elaborate extend:

- 1) This investigation was conducted in the light of the merger between the Onze-Lieve-Vrouwe-Gasthuis (OLVG) and the Sint Lucas Andreas hospital in Amsterdam. Given that this thesis only investigates the instrument sterilization cycle from the perspective of the former OLVG we

recommend that a similar investigation is also conducted in the former Sint Lucas Andreas as well. In this way the current states of the sterilization cycles can be compared in great detail, allowing for a discussion of how these separate sterilization cycles should be merged.

- 2) In chapter 5 we created a demand forecasting model based on past procedure demand. Because the procedures were conducted over both hospital locations prior to March 2017, we were only able to make use of a limited dataset of 14 weeks to build our forecasting model as a proof of principle. In chapter 5 we utilized the data in such a fashion that the first 10 weeks of this dataset were used to generate a forecast and the last four weeks were used to measure forecasting accuracy. By doing so we were able to generate a forecast with a calculated MASE accuracy of 0.98 according to the Pareto principle. For future reference it would be interesting to see if this accuracy can be improved by extending both the time frame of forecast generation and the time frame for forecast accuracy measurement.
- 3) If the OLVG would consider utilizing past tray demand in order to simplify forecasting, we recommended that the OLVG should make use of the datasets that can currently be provided by the Clinium CSSD. Before doing so, however, the OLVG will have to look into the recorded throughput differences between the EPF, OR Tracing and CSSD T&T systems to make sure that the CSSD data is valid and reliable.
- 4) Not mentioned in chapter 5, but still worth a recommendation is that the OLVG should investigate how a platform for informed debate about instrument tray contents can be organized. This should be done in consultation with the medical staff in order to achieve the best possible results.
- 5) In chapter 6 we examined the financial considerations of implementing either RFID or UDI compliant barcodes. In this investigation we found ourselves unable to quantify the difference in financial benefits by employing either of the two technologies. In the case of RFID implementation we assume that especially the bulk scanning without a clear line of sight might result into significant operational benefits. We therefore recommend the OLVG to conduct an investigation into this topic.
- 6) Last we recommend that the OLVG investigate whether the barcode labels and RFID tags currently used on the instrument trays can be integrated seamlessly into a new IT environment. This assumption was placed central in the examination of the cost consideration but was not investigated in detail.

8. References

- [1] Stichting OLVG, “Maatschappelijk verslag en jaarrekening,” Amsterdam, 2016.
- [2] Stichting OLVG, “Jaarverantwoording 2015 Jaarverslag & jaarrekening,” Amsterdam, 2015.
- [3] Centraal Bureau voor de Statistiek, “Bevolkingsontwikkeling; regio Amsterdam per maand,” 2017.
- [4] Zorgkaart Nederland, “Ziekenhuizen in Amsterdam.” [Online]. Available: <https://www.zorgkaartnederland.nl/ziekenhuis/amsterdam>. [Accessed: 10-Aug-2017].
- [5] Y. A. Ozcan, *Quantitative Methods In Healthcare Management: Techniques and applications*, 2nd ed., no. May. San Francisco: Jossey-Bass, 2009.
- [6] E. Abukhousa, J. Al-jaroodi, S. Lazarova-molnar, and N. Mohamed, “Simulation and Modeling Efforts to Support Decision Making in Healthcare Supply Chain Management,” *Sci. J.*, vol. 2014, p. 16, 2014.
- [7] B. Kamphorst, “Optimalisatie van de samenstelling van steriele medische instrumentennetten,” Universiteit Twente, 2012.
- [8] BovenIJ Ziekenhuis, “BovenIJ-geschiedenis,” 2017. [Online]. Available: https://www.bovenij.nl/BovenIJ/Wie_zijn_wij/BovenIJ-geschiedenis.html. [Accessed: 10-Aug-2017].
- [9] ANP/ Parool, “Slotervaartziekenhuis viert 35 jarig bestaan met boek,” *Parool*, Amsterdam, 26-Jul-2011.
- [10] ANP/ Parool, “Meer onderzoek naar fusie AMC en VUmc - Amsterdam - PAROOL,” *Parool*, Amsterdam, pp. 15–17, 14-Dec-2016.
- [11] R. A. Kuthy, J. C. Reynolds, S. C. McKernan, and P. C. Damiano, “Rise of Managed Care in the USA: Lessons for Dentistry,” *Curr. Oral Heal. Reports*, pp. 1–9, 2016.
- [12] C. van Weel, H. Schers, and A. Timmermans, “Health care in the Netherlands,” *J. Am. Board Fam. Med.*, vol. 25, no. April, p. S12–7 1p, 2012.
- [13] M. Porter and R. S. Kaplan, “How should we pay for healthcare,” *Hbr*, 2015.
- [14] S. M. Weiss, R. E. Malone, J. R. Merighi, S. M. Weiss, R. E. Malone, J. R. Merighi, and P. Benner, “Economism, Efficiency, and the Moral Ecology of Good Nursing Practice,” *CJNR*, vol. 41, pp. 340–364, 2009.
- [15] T. Kristensen, P. Bogetoft, and K. M. Pedersen, “Potential gains from hospital mergers in Denmark,” *Health Care Manag. Sci.*, vol. 13, no. 4, pp. 334–345, 2010.
- [16] J. Harris, H. Ozgen, and Y. Ozcan, “Do mergers enhance the performance of hospital efficiency?,” *J. Oper. Res. Soc.*, vol. 51, no. 7, pp. 801–811, Jul. 2000.
- [17] F. Schotanus and J. Telgen, “Developing a typology of organisational forms of cooperative purchasing,” *J. Purch. Supply Manag.*, vol. 13, no. 1, pp. 53–68, 2007.
- [18] W. P. van Amstel, “Het organiseren van logistieke beheersing,” Vrije Universiteit Amsterdam, 2002.
- [19] B. L. Hintzen, S. J. Knoer, C. J. van Dyke, and B. S. Milavitz, “Effect of lean process improvement

techniques on a university hospital inpatient pharmacy," *Am J Heal. Pharm*, vol. 66, pp. 2042–2047, 2009.

- [20] D. Nave, "How to Compare Six Sigma, Lean Management, and the Theory of Constraints," *Qual. Process*, vol. 35, pp. 73–78, 2002.
- [21] A. C. Guédon, T. J. Rakers, L. S. G. L. Wauben, F. C. Meeuwssen, V. Hoeijmans, M. van der Elst, J. Dankelman, and J. J. van den Dobbelsteen, "Just-in-time delivery of sterilised surgical instruments," *BMJ Innov.*, vol. 2, no. 2, pp. 58–64, 2016.
- [22] A. J. Mangram, T. C. Horan, M. L. Pearson, L. C. Silver, W. R. Jarvis, and C. Hosp Infect Control Practices Advisory, "Guideline for prevention of surgical site infection, 1999," *Am. J. Infect. Control*, vol. 27, no. 2, pp. 97–132, 1999.
- [23] D. G. Katehakis and M. Tsiknakis, "Electronic health record," *Int. J. Med. Inform.*, vol. 83, no. 11, pp. 779–796, 2006.
- [24] T. Barker and M. N. Frolick, "Erp Implementation Failure: A Case Study, Information Systems Management," *Inf. Syst. Manag.*, vol. 20, no. 4, pp. 43–49, 2003.
- [25] D. A. van Damme, "Distributielogistiek & financiële informatie," Technische Universiteit Eindhoven, 2000.
- [26] M. A. Cusumano, "The limits of Lean," *Sloan Manage. Rev.*, 1994.
- [27] P. Hines, M. Holweg, and N. Rich, "Learning to evolve: A review of contemporary lean thinking Peter," *Int. J. Oper. Prod. Manag.*, vol. 24, no. 10, pp. 994–1011, Oct. 2004.
- [28] D. Nave, "How to Compare Six Sigma, Lean Management, and the Theory of Constraints," *Qual. Process*, vol. 35, pp. 73–78, 2002.
- [29] C. S. Kim, D. A. Spahlinger, J. M. Kin, and J. E. Billi, "Lean Health Care : What Can Hospitals Learn from a World-Class Automaker ?," *J. Hosp. Med.*, vol. 1, pp. 191–199, 2006.
- [30] J. C. Chen, Y. Li, and B. D. Shady, "From value stream mapping toward a lean/sigma continuous improvement process: an industrial case study," *Int. J. Prod. Res.*, vol. 48, no. 4, pp. 1069–1086, 2010.
- [31] A. Fearne, M. Garcia, M. Benjamin, A. Fearne, M. G. Martinez, and B. Dent, "Invited paper Dimensions of sustainable value chains : implications for value chain analysis," 2014.
- [32] G. Wang, S. H. Huang, and J. P. Dismukes, "Product-driven supply chain selection using integrated multi-criteria decision-making methodology," *Int. J. Prod. Econ.*, vol. 91, no. 1, pp. 1–15, Sep. 2004.
- [33] D. Ivanov, B. Sokolov, and J. Kaeschel, "A multi-structural framework for adaptive supply chain planning and operations control with structure dynamics considerations," *Eur. J. Oper. Res.*, vol. 200, no. 2, pp. 409–420, 2010.
- [34] D. Li and C. O'Brien, "Integrated decision modelling of supply chain efficiency," *Int. J. Prod. Econ.*, vol. 59, no. 1, pp. 147–157, 1999.
- [35] Maulik S. Joshi, E. R. Ransom, D. B. Nash, and S. B. Ransom, "The Healthcare Quality Book: Vision, Strategy, and Tools," in *The Healthcare Quality Book: Vision, Strategy, and Tools, Third edition*,

Third Edit., HAP, 2014, pp. 185–186.

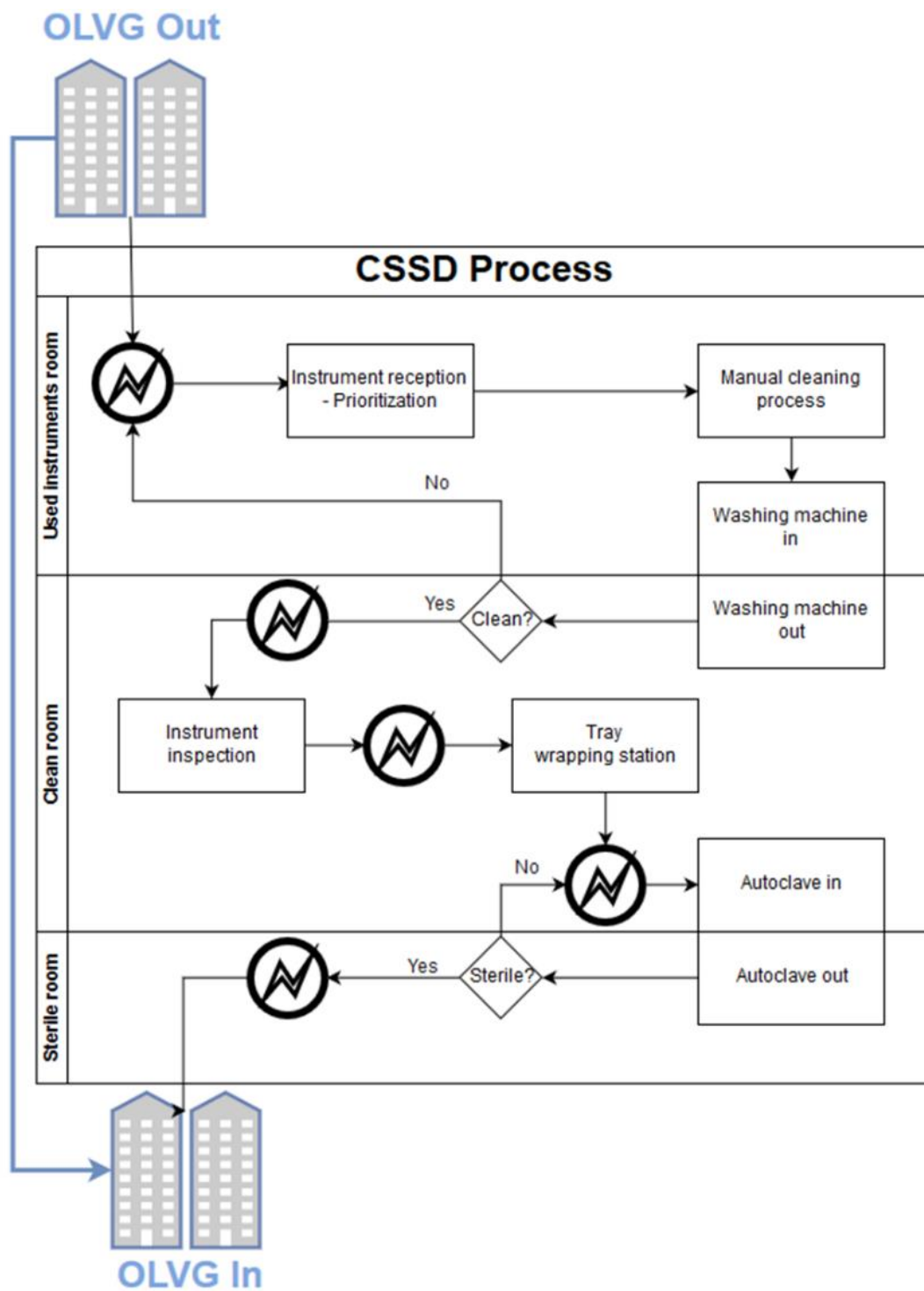
- [36] H. L. Lee and C. Billington, “Managing Supply Chain Inventory : Pitfalls and Opportunities,” *Sloan Manage. Rev.*, vol. 33, no. 3, p. 65, 1992.
- [37] S. . Campbell, M. . Roland, and S. . Buetow, “Defining quality of care,” *Soc. Sci. Med.*, vol. 51, no. 11, pp. 1611–1625, Dec. 2000.
- [38] L. Wyszewianski, “Defining, measuring, and improving quality of care,” *Clin. Fam. Pract.*, vol. 5, no. 4, pp. 807–825, Dec. 2003.
- [39] J. Gosling and M. M. Naim, “Engineer-to-order supply chain management: A literature review and research agenda,” *Int. J. Prod. Econ.*, vol. 122, no. 2, pp. 741–754, 2009.
- [40] E. W. Hans, M. van Houdenhoven, and P. J. H. Hulshof, “A Framework for Healthcare Planning and Control,” in *Handbook of Healthcare System Scheduling*, no. January, Springer Science & Business Media., 2012.
- [41] R. C. Hicks, R. Dattero, and S. D. Galup, “The five-tier knowledge management hierarchy,” *J. Knowl. Manag.*, vol. 10, no. 1, pp. 19–31, 2006.
- [42] M. J. Cote and S. L. Tucker, “Four Methodologies to Improve Healthcare Demand Forecasting,” *Healthc. Financ. Manag.*, p. 54, 2001.
- [43] Nederlandse Zorgautoriteit, “Wat is een DBC,” 2017. [Online]. Available: <http://werkenmetdbcs.nza.nl/geriatrische-revalidatiezorg-artikelen/dbc-systematiek-6/wat-is-een-dbc-4/menu-ID-2015>. [Accessed: 02-Jul-2017].
- [44] C. Goh and R. Law, “Modeling and forecasting tourism demand for arrivals with stochastic nonstationary seasonality and intervention,” *Tour. Manag.*, vol. 23, no. 5, pp. 499–510, 2002.
- [45] R. Carbonneau, K. Laframboise, and R. Vahidov, “Application of machine learning techniques for supply chain demand forecasting,” *Eur. J. Oper. Res.*, vol. 184, no. 3, pp. 1140–1154, 2008.
- [46] E. Litvak, P. I. Buerhaus, F. Davidoff, M. C. Long, M. L. McManus, and D. M. Berwick, “Managing unnecessary variability in patient demand to reduce nursing stress and improve patient safety.,” *Jt Comm J Qual Patient Saf*, vol. 31, no. 6, pp. 330–338, 2005.
- [47] K. J. Livak and T. D. Schmittgen, “Analysis of relative gene expression data using real-time quantitative PCR and the $2^{-(\Delta\Delta CT)}$ method.,” *Methods*, vol. 25, no. 4, pp. 402–408, 2001.
- [48] A. H. Briggs, M. C. Weinstein, E. a L. Fenwick, J. Karnon, M. J. Sculpher, and a D. Paltiel, “Model parameter estimation and uncertainty analysis: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force Working Group-6.,” *Med. Decis. Making*, vol. 32, no. 5, pp. 722–32, 2012.
- [49] L. Castro, E. Lefebvre, and L. A. Lefebvre, “Adding Intelligence to Mobile Asset Management in Hospitals : The True Value of RFID,” *J Med Syst*, vol. 37, 2013.
- [50] C. Liao and C. Shyu, “An Analytical Determination of Lead Time with Normal Demand,” vol. 11, no. 9, pp. 72–78, 1991.
- [51] J. E. Tyworth and L. O. ’ Neill, “Robustness of the Normal Approximation of Lead - Time Demand in a Distribution Setting,” *Nav. Res. Logist.*, vol. 44, pp. 165–186, 1997.

- [52] G. Grimmett and D. Welsh, *Probability: an introduction*. Oxford Science Publications, 2014.
- [53] B. E. Flores and D. C. Whybark, "Implementing multiple criteria ABC analysis," *J. Oper. Manag.*, vol. 7, no. 1–2, pp. 79–85, 1987.
- [54] J. Huiskonen, "Maintenance spare parts logistics : Special characteristics and strategic choices," *Int. J. Prod. Econ.*, vol. 71, no. February 2001, pp. 125–133, 2001.
- [55] R. J. Hyndman and A. B. Koehler, "Another look at measures of forecast accuracy," *Int. J. Forecast.*, vol. 22, no. 4, pp. 679–688, 2006.
- [56] R. Hyndman, "Another Look At Forecast-Accuracy Metrics for Intermittent Demand," *Foresight Int. J. Appl. Forecast.*, no. 4, pp. 43–46, 2006.
- [57] W. B. Rouse, "Health care as a complex adaptive system: implications for design and management," *Bridg. Acad. Eng.*, vol. 38, no. 1, p. 17, 2008.
- [58] M. D. Joshi, E. R. Ransom, D. B. Nash, and S. B. Ransom, *The Healthcare Quality Book - Vision, Strategy and Tools*, Third edit. Health Administration Press, 2014.
- [59] Florida Institute of Technology, "Supply Chain Management vs . Operations Management," *Florida Institute of Technology*, 2017. [Online]. Available: <https://www.floridatechonline.com/blog/process-improvement/supply-chain-management-vs-operations-management/%0ARead>. [Accessed: 12-May-2017].
- [60] T. Pizzuti, G. Mirabelli, M. A. Sanz-Bobi, and F. Gómez-González, "Food Track & Trace ontology for helping the food traceability control," *J. Food Eng.*, vol. 120, no. 1, pp. 17–30, 2014.
- [61] Woodland, "Classifying apparatus and method," 1952.
- [62] T. Ebel, Katy George, E. Larsen, E. Neal, K. Shah, and D. Shi, "Strength in unity: The promise of global standards in healthcare," 2012.
- [63] H. G. Adams and A. F. Campbell, "Automated Technology Report Generation Using Barcode," *AJR*, vol. 145, no. July, pp. 177–180, 1985.
- [64] J. Z. Gao, L. Prakash, and R. Jagatesan, "Understanding 2D-BarCode Technology and Applications in M-Commerce – Design and Implementation of A 2D Barcode Processing Solution," no. Compsac, pp. 0–7, 2007.
- [65] H. Kato and K. T. Tan, "Pervasive 2D Barcodes for Camera Phone Applications," 2007.
- [66] GS1 - The Netherlands, "Veelgestelde vragen UDI-wetgeving," *Wat is het verschil tussen een GS1 DataMatrix en een GS1 QR?* [Online]. Available: <https://www.gs1.nl/udi-wetgeving/veelgestelde-vragen-udi-wetgeving>. [Accessed: 26-May-2017].
- [67] N. C. Wu, M. A. Nystrom, T. R. Lin, and H. C. Ñ. Yu, "Challenges to global RFID adoption," vol. 26, pp. 1317–1323, 2006.
- [68] J. Qian, X. Yang, X. Wu, L. Zhao, B. Fan, and B. Xing, "A traceability system incorporating 2D barcode and RFID technology for wheat flour mills," *Comput. Electron. Agric.*, vol. 89, pp. 76–85, 2012.
- [69] Lu Yan et al., *The Internet of things: from RFID to the next-generation pervasive networked systems*. CRC Press, 2008.

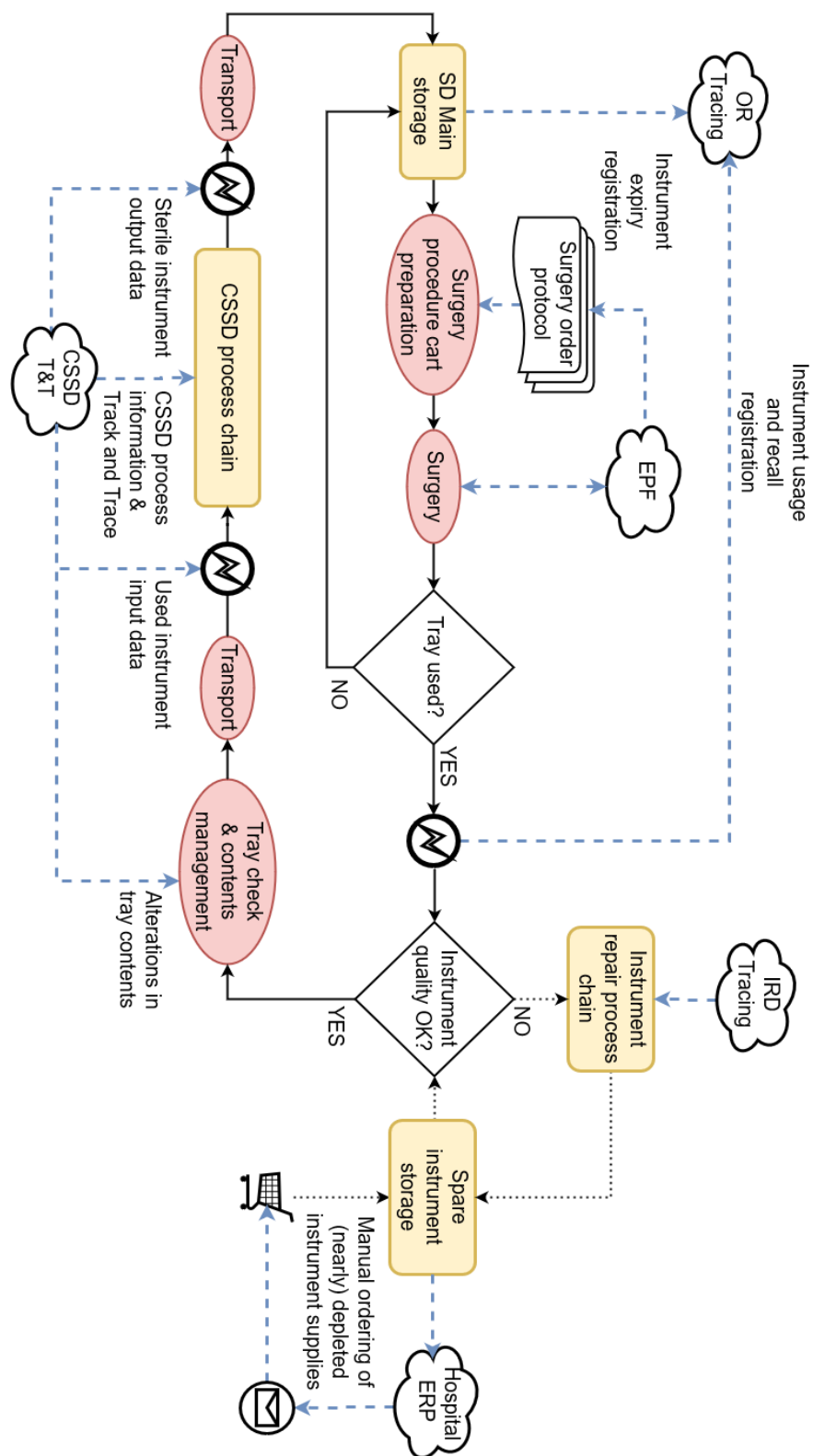
- [70] M. M. Aung and Y. S. Chang, "Traceability in a food supply chain : Safety and quality perspectives," *Food Control*, vol. 39, pp. 172–184, 2014.
- [71] R. Koh, E. W. Schuster, I. Chackrabarti, and A. Bellman, "Securing the Pharmaceutical Supply Chain," *Auto-ID Cent.*, 2003.
- [72] IMDRF UDI Working Group, "UDI guidance: Unique Device Identification (UDI) of medical devices," 2013.
- [73] FDA, "UDI Basics," 2013. [Online]. Available: <https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/udidbasics/default.htm>.
- [74] Medtech Europe, "European Unique Device Identification Database (EUDID)," no. June, 2014.
- [75] EU parliament, *Publicatieblad L 117*, vol. 60. 2017.
- [76] S. Kumar, G. Livermont, and G. McKewan, "Stage implementation of RFID in hospitals," *Technol. Heal. Care*, vol. 18, no. 1, pp. 31–46, 2010.
- [77] K. L. Hulebak and W. Schlosser, "Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview," vol. 22, no. 3, 2002.
- [78] D. Bansal, S. Malla, K. Gudala, and P. Tiwari, "Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective," *Sci Pharm.*, vol. 81, pp. 1–13, 2013.
- [79] M. Schmidt, M. Schumann, and M. Schumann, "Co-existence of RFID and Barcode in Automotive Logistics," *AMCIS 2010 Proc.*, vol. 84, 2010.
- [80] P. V Nikitin and K. V. S. Rao, "Antenna Design for UHF RFID Tags: A Review and a Practical Application"," *IEEE Trans. Antennas Propag.*, vol. 54, no. 6, pp. 1906–1907, 2006.
- [81] European Commission, *The "Blue Guide" on the implementation of EU products rules 2016*, vol. 2016. European commission, 2016.
- [82] W. Yao, C. H. Chu, and Z. Li, "The adoption and implementation of RFID technologies in healthcare: A literature review," *J. Med. Syst.*, vol. 36, no. 6, pp. 3507–3525, 2012.
- [83] C. CSSD, *Business Case uitbesteden OK Logistiek OLVG*. 2016, pp. 1–20.
- [84] GS1, *Patiëntveiligheid en efficiency in de OK (businesscase)*. 2011, pp. 1–48.

9. Supplementary material

9.1. Supplement 1 – Logistics cycle of the CSSD process



9.2. Supplement 2 – Expanded view of the instrument sterilization cycle



9.3. Supplement 3 – Control criteria for the instrument sterilization cycle

No.	Criterion	Description
1	Instrument tray composition	Are all required instruments accounted for?
2	Instrument safety and functionality	Are all instruments safe to work with (no leakage, burrs, rust) and does it do what it is designed to do?
3	Instrument sterility	Is instrument (tray) sterility guaranteed and monitored?
4	Process timeliness	Are processes primed for speed and efficiency? Are stocks replenished in time without the need for rush-orders?
5	Process complexity	Are processes primed for simplicity or do they require a lot of work-arounds? Do the corresponding software systems facilitate simplicity?
6	Physical workload	Do the processes require a lot of manual labor and/or heavy lifting?
7	Inventory management accuracy	Is inventory management heavily reliant on personnel expertise? Is the process error prone? Are abnormalities in supply registration encountered frequently?
8	Track and traceability of supplies	Does the system have capabilities to track and trace instruments? Is the usage of instruments coupled to patients and/or specialists? Does the system give an accurate picture of instrument usage?
9	System flexibility	Is the system flexible enough to deal with surgery production peaks without rush-orders? Is overstocking used as a shortage avoidance strategy?

9.4. Supplement 4 – Amount of trays required Pareto principle

Work week OLVG (days)	5
Clinium operation (hours/day)	24
Work week in sterilization cycle (hours)	120

Row Labels	Poisson Lambda per instrument tray	Required k trays for cumulative probability ≥ 97,5%	Voorrang (0/1)	Cycle time (h)	#No. of cycles per week	#No. of trays in cycle
BASIS NET	0,5	2	0	34	4,94	1
CYSTOSCOPIE 22.5 FR 12° 30° OK URO	0,2	1	0	34	4,94	1
DERMATOOM ELECTRISCH TBV DE SOUTTER CONSOLE	0	0	0	34	4,94	0
FIJN INSTRUMENT B.BRAUN	0	0	0	34	4,94	0
MESHGRAFT II MET SLINGER (ZIMMER)	0	0	0	34	4,94	0
OK DERMATOOM 315MM COBBETT (HUMBY)	0	0	0	34	4,94	0
OK GRAFTBOARD 166X116MM (SPANPLAAT HUID)	0	0	0	34	4,94	0
OLVG - PNL Alken dilatatoren set	0	0	0	34	4,94	0
OLVG 30° graden optiek 10 mm Stryker	0	0	0	34	4,94	0
OLVG Albaran 2-weg P.URO	0	0	0	34	4,94	0
OLVG Anale Knots, 25mm EEA- 25	0	0	0	34	4,94	0
OLVG Anale knots, 28mm EEA- 28	0	0	0	34	4,94	0
OLVG Balfourspreider	0	0	0	34	4,94	0
OLVG Basis net	0	0	0	34	4,94	0
OLVG Bi-polair Tur set + optiek 12° A22001A 07J	8,9	15	0	34	4,94	4
OLVG Bi-polair Tur set + optiek 12° A22001A H60	0,4	2	0	34	4,94	1
OLVG Bougies middel	0	0	0	34	4,94	0
OLVG Calcutript netje	0	0	0	34	4,94	0
OLVG Chirurgisch net	0	0	0	34	4,94	0
OLVG Cliptang medium 9503p- 236e blauw	0	0	0	34	4,94	0
OLVG Cysto-Uretheroscoop 30° VOORRANGSSET	7,7	14	1	15	11,20	2
OLVG Darmklem verend, EA 202/203	0,1	1	0	34	4,94	1

OLVG Diathermie verlengstuk	0	0	0	34	4,94	0
OLVG Diathermiesnoer OK ALG	0	0	0	34	4,94	0
OLVG Dilatoren set DC	0	0	0	34	4,94	0
OLVG Endo Eye Video URS VOORRANGSSET	1,8	5	1	15	11,20	1
OLVG Flexibele bioptieang 9 FR27175 B	3,9	8	0	34	4,94	2
OLVG Hem-O-Cliptang XL VOORRANGSSET	0	0	1	15	11,20	0
OLVG Hem-o-lok cliptang L	0	0	0	34	4,94	0
OLVG Hem-o-lok cliptang ML	0	0	0	34	4,94	0
OLVG Klein chir. net	0	0	0	34	4,94	0
OLVG Klein urologisch setje VOORRANGSNET	1,1	4	1	15	11,20	1
OLVG Klein Vaginaal Netje	0	0	0	34	4,94	0
OLVG L.A.V.H. set	0	0	0	34	4,94	0
OLVG Lampendop OK ALG VOORRANG	0	0	1	15	11,20	0
OLVG Lap. prepareerklem 90° 10mm VOORRANG	0	0	1	15	11,20	0
OLVG Laparoscoop 0° 10 mm	0	0	0	34	4,94	0
OLVG Laparoscoop 30° 10mm Stryker	0	0	0	34	4,94	0
OLVG Laparoscopische Babcock	0	0	0	34	4,94	0
OLVG Laparotomie net	0	0	0	34	4,94	0
OLVG Laserstripper URS	3,9	8	0	34	4,94	2
OLVG Lichtkabel OK ALG	0	0	0	34	4,94	0
OLVG Lichtkabel PAARS OK URO	0	0	0	34	4,94	0
OLVG Litho Clast net	0,4	2	0	34	4,94	1
OLVG Lithoclast Trilsondes	0,4	2	0	34	4,94	1
OLVG Lithotriptortang Olympus A3661	0,4	2	0	34	4,94	1
OLVG Maatbeker 1000 ml	5,7	11	0	34	4,94	3
OLVG Maatbeker 3000 ml	2,7	6	0	34	4,94	2
OLVG Magneet Uro	0	0	0	34	4,94	0
OLVG Magneetmat	0,3	2	0	34	4,94	1
OLVG Mamma net	0	0	0	34	4,94	0
OLVG Millin instrumentarium	0,3	2	0	34	4,94	1
OLVG MyTube	0	0	0	34	4,94	0
OLVG Optiek 0° urologie	0	0	0	34	4,94	0
OLVG Optiek 30° P.URO	0	0	0	34	4,94	0
OLVG Optiek 30° URO	2,6	6	0	34	4,94	2
OLVG PNL net	0,4	2	0	34	4,94	1

OLVG PNL net extra lang	0,4	2	0	34	4,94	1
OLVG PNL Paktangen	0,4	2	0	34	4,94	1
OLVG Sachse	0	0	0	34	4,94	0
OLVG Sachse mesje recht 27069 K	0,6	2	0	34	4,94	1
OLVG Sachse net	0,6	2	0	34	4,94	1
OLVG Specula net URO	0	0	0	34	4,94	0
OLVG TVT Set	0	0	0	34	4,94	0
OLVG Urologisch basis VOORRANGSNET	2,8	6	1	15	11,20	1
OLVG Urologisch net	0,3	2	0	34	4,94	1
OLVG Urologisch net extra lang	0	0	0	34	4,94	0
OLVG URS net VOORRANGSSET	7,3	13	1	15	11,20	2
OLVG URS Scoop VOORRANGSNET	3,9	8	1	15	11,20	1
OLVG Uterus manipulator VOORRANGSSET	0	0	1	15	11,20	0
OLVG Uteruskantelaar+conusopzetstuk OK GYN	0	0	0	34	4,94	0
OLVG Verwijdertang dubbel J cath.	7,3	13	0	34	4,94	3
OLVG Voersonde injector needle 27G URO	0	0	0	34	4,94	0
OLVG Waskom	0	0	0	34	4,94	0
OLVG Werkscoopnet 1/2	0	0	0	34	4,94	0
OLVG Werkscoopnet 2/2	0	0	0	34	4,94	0
OLVG Zelfspreider stomp BV 075R	0,1	1	0	34	4,94	1
OLVG Zelfspreider Weitlaner, stomp BV 207	0	0	0	34	4,94	0
VAGINAAL NET KLEIN	0	0	0	34	4,94	0

9.5. Supplement 5 – Amount of trays required 90% of procedure demand

1. Work week OLVG (days)	5
Clinium operation (hours/day)	24
Work week in sterilization cycle (hours)	120

Row Labels	Poisson Lambda per instrument tray	Required k trays for cumulative probability ≥ 97,5%	Voorrang (0/1)	Cycle time (h)	#No. of cycles per week	#No. of trays in cycle
BASIS NET	0,5	2	0	34	4,94	1
CYSTOSCOPIE 22.5 FR 12° 30° OK URO	0,2	1	0	34	4,94	1
DERMATOOM ELECTRISCH TBV DE SOUTTER CONSOLE	0	0	0	34	4,94	0
FIJN INSTRUMENT B.BRAUN	0	0	0	34	4,94	0
MESHGRAFT II MET SLINGER (ZIMMER)	0	0	0	34	4,94	0
OK DERMATOOM 315MM COBBETT (HUMBY)	0	0	0	34	4,94	0
OK GRAFTBOARD 166X116MM (SPANPLAAT HUID)	0	0	0	34	4,94	0
OLVG - PNL Alken dilatatoren set	0	0	0	34	4,94	0
OLVG 30° graden optiek 10 mm Stryker	0	0	0	34	4,94	0
OLVG Albaran 2-weg P.URO	0	0	0	34	4,94	0
OLVG Anale Knots, 25mm EEA- 25	0	0	0	34	4,94	0
OLVG Anale knots, 28mm EEA- 28	0	0	0	34	4,94	0
OLVG Balfourspreider	0,1	1	0	34	4,94	1
OLVG Basis net	0	0	0	34	4,94	0
OLVG Bi-polair Tur set + optiek 12° A22001A 07J	9,1	15	0	34	4,94	4
OLVG Bi-polair Tur set + optiek 12° A22001A H60	0,4	2	0	34	4,94	1
OLVG Bougies middel	0,2	1	0	34	4,94	1
OLVG Calcutript netje	0	0	0	34	4,94	0
OLVG Chirurgisch net	0	0	0	34	4,94	0
OLVG Cliptang medium 9503p- 236e blauw	0	0	0	34	4,94	0
OLVG Cysto-Uretheroscoop 30° VOORRANGSSET	8,7	15	1	15	11,20	2
OLVG Darmklem verend, EA 202/203	0,1	1	0	34	4,94	1

OLVG Diathermie verlengstuk	0,1	1	0	34	4,94	1
OLVG Diathermiesnoer OK ALG	0	0	0	34	4,94	0
OLVG Dilatoren set DC	0	0	0	34	4,94	0
OLVG Endo Eye Video URS VOORRANGSSET	2,7	6	1	15	11,20	1
OLVG Flexibele bioptieang 9 FR27175 B	4	8	0	34	4,94	2
OLVG Hem-O-Cliptang XL VOORRANGSSET	0	0	1	15	11,20	0
OLVG Hem-o-lok cliptang L	0,1	1	0	34	4,94	1
OLVG Hem-o-lok cliptang ML	0,1	1	0	34	4,94	1
OLVG Klein chir. net	0	0	0	34	4,94	0
OLVG Klein urologisch setje VOORRANGSNET	1,1	4	1	15	11,20	1
OLVG Klein Vaginaal Netje	0	0	0	34	4,94	0
OLVG L.A.V.H. set	0	0	0	34	4,94	0
OLVG Lampendop OK ALG VOORRANG	0,1	1	1	15	11,20	1
OLVG Lap. prepareerklem 90° 10mm VOORRANG	0	0	1	15	11,20	0
OLVG Laparoscoop 0° 10 mm	0,1	1	0	34	4,94	1
OLVG Laparoscoop 30° 10mm Stryker	0	0	0	34	4,94	0
OLVG Laparoscopische Babcock	0	0	0	34	4,94	0
OLVG Laparotomie net	0	0	0	34	4,94	0
OLVG Laserstripper URS	4,9	10	0	34	4,94	3
OLVG Lichtkabel OK ALG	0	0	0	34	4,94	0
OLVG Lichtkabel PAARS OK URO	0	0	0	34	4,94	0
OLVG Litho Clast net	0,4	2	0	34	4,94	1
OLVG Lithoclast Trilsondes	0,4	2	0	34	4,94	1
OLVG Lithotriptortang Olympus A3661	0,4	2	0	34	4,94	1
OLVG Maatbeker 1000 ml	5,7	11	0	34	4,94	3
OLVG Maatbeker 3000 ml	2,9	7	0	34	4,94	2
OLVG Magneet Uro	0	0	0	34	4,94	0
OLVG Magneetmat	0,4	2	0	34	4,94	1
OLVG Mamma net	0	0	0	34	4,94	0
OLVG Millin instrumentarium	0,3	2	0	34	4,94	1
OLVG MyTube	0	0	0	34	4,94	0
OLVG Optiek 0° urologie	0	0	0	34	4,94	0
OLVG Optiek 30° P.URO	0	0	0	34	4,94	0
OLVG Optiek 30° URO	2,7	6	0	34	4,94	2
OLVG PNL net	0,4	2	0	34	4,94	1

OLVG PNL net extra lang	0,4	2	0	34	4,94	1
OLVG PNL Paktangen	0,4	2	0	34	4,94	1
OLVG Sachse	0	0	0	34	4,94	0
OLVG Sachse mesje recht 27069 K	0,6	2	0	34	4,94	1
OLVG Sachse net	0,6	2	0	34	4,94	1
OLVG Specula net URO	0,1	1	0	34	4,94	1
OLVG TVT Set	0,4	2	0	34	4,94	1
OLVG Urologisch basis VOORRANGSNET	3,3	7	1	15	11,20	1
OLVG Urologisch net	0,3	2	0	34	4,94	1
OLVG Urologisch net extra lang	0	0	0	34	4,94	0
OLVG URS net VOORRANGSSET	7,4	13	1	15	11,20	2
OLVG URS Scoop VOORRANGSNET	4,9	10	1	15	11,20	1
OLVG Uterus manipulator VOORRANGSSET	0	0	1	15	11,20	0
OLVG Uteruskantelaar+conusopzetstuk OK GYN	0	0	0	34	4,94	0
OLVG Verwijdertang dubbel J cath.	8,3	14	0	34	4,94	3
OLVG Voersonde injector needle 27G URO	0	0	0	34	4,94	0
OLVG Waskom	0	0	0	34	4,94	0
OLVG Werkscoopnet 1/2	0	0	0	34	4,94	0
OLVG Werkscoopnet 2/2	0	0	0	34	4,94	0
OLVG Zelfspreider stomp BV 075R	0,1	1	0	34	4,94	1
OLVG Zelfspreider Weitlaner, stomp BV 207	0,1	1	0	34	4,94	1
VAGINAAL NET KLEIN	0,4	0	0	34	4,94	0