Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Engineering
Department of Mechanical and Industrial Engineering

Elise Keseler

The Hospital Logistics of Designing the Central Sterile Processing Department

- From the inside and out

Master's thesis in Mechanical Engineering
Supervisor: Jan Ola Strandhagen
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NTNU
Norwegian University of
Science and Technology

Summary

The sterile processing logistics are among the supporting activities that have been recognized to have a great impact on the overall efficiency of a health care system. It comprises activities that are both cost- and labour-intensive and therefore incurs a high opportunity cost for many hospitals. The Central Sterile Processing Department provides the required trays of instruments, in the required condition, at a rate that supports the operation schedule and procedures of the hospital. The services delivered by the CSPD are directly linked to patient safety.

The performance of the CSPD depends on its process design, and the strategical decisions made when designing the department. The process design aims to assure that the processes perform accordingly to the objectives it seeks to achieve, while the strategical decisions are concerned with making the associated long-term design commitments. The Central Sterile Processing Department must deliver the required sterile goods for both planned and unplanned treatments. At times the department has difficulties maintaining high service levels, due to capacity issues. If not designed and planned correctly the CSPD could end up being a limiting resource within the hosptial.

This thesis will investigate what the important design decisions, related to planning the process design of the CSPD, are. In order make valid design decisions and provide satisfactory results, the necessary information must be available at the right time in the planning process. To facilitate for this, the thesis will further investigate how a systematic procedure for designing the CSPD could provide CSPD designs that are fit to meet future requirements. The overall research goal of the thesis is to facilitate for process designs that are planned from the inside out, to make the functionality of the CSPD a priority when strategic decisions are made. In order to do so, the following research questions were answered:

RQ1: *What are the design decisions involved when designing the processes of a Central Sterile Processing department?*

RQ2: *How can a systematic design procedure facilitate for CSPD designs that meet the future requirements?*

The research design applied is a combination of a literature study and two case studies. The first case provided insight to the project of planning a new CSPD at Stavanger University Hospital. The second case gave understanding of how the process design has impacted the operational performance of the CSPD at St. Olav Hospital.

Based on findings from the literature and case studies, important design decisions have been identified. The long-term strategical decisions related to the process design of the CSPD are concerned with its location, long-term capacity and size requirements, layout and the environmental requirements of a CSPD. The operational decisions are related to the choice of service design, technology and the organization and job-design of the CSPD staff. It is identified how the decisions are highly correlated, and dependant on both external and internal factors of influence. The process of decision making is therefore knowledge intensive for the hospital planners. The design process is identified as highly iterative and especially challenging when the right information is not available at the right time to support the decisions when they must be taken There is reason to believe that applying a systematic design procedure to coordinate the process of planning the CSPD would have a positive impact on both the planning process and the resulting designs. There is a lack such a procedure, both in literature and in practise.

The thesis contributes with a suggested six-step to systematic design procedure for the CSPD process design. Applying such a procedure could help coordinate the different actors involved in the design process. It provides an overview of what information needs to be collected before important design decisions are made. An earlier understanding of the objectives, functions and capacity requirement of the CSPD design could be decisive for the end results and serve as important input for determining the final dimensions of the CSPD. In this way, the systematic design procedure can help facilitating for designing the CSPD from the inside and out, with functionality as the priority when strategic decisions are being made. How well suited the designs will be to meet the future requirements is additionally highly dependent on the quality of the analyses, forecasts and the input provided. But a systematic design procedure can help pave the way for decisionmakers and provide them with the best prerequisites for developing CSPD process designs better equipped to meet future requirements.

Sammendrag

Sterilprosessering er blant støttefunksjonene som er kjent for å ha stor innflytelse på den helhetlige effektiviteten i sykehusene. Sterilprosessering er både kostnads og arbeidskrevende, forbedring av prosessene involvert medfører derfor potensiale for innsparing hos sykehusene. Sterilsentralen sin oppgave er å levere riktig utstyr, i riktig tilstand og til riktig tid, for å understøtte operasjonsplanen og prosedyrene utført på sykehuset. Tjenestene levert av sterilsentralen er med dermed direkte knyttet til pasientenes sikkerhet.

Hvor godt sterilsentralen presterer er direkte knyttet til prosessdesignet og de strategiske avgjørelsene som fattes i prosessen med å designe den. Prosessdesignet skal legge til rette for at sterilsentralen presterer i samsvar med dens målsetninger. De strategiske avgjørelsene handler om å ta de riktige langsiktige avgjørelsene for å oppnå dette. Sterilsentralen må levere det nødvendige utstyret til både planlagte og uplanlagte pasientbehandlinger. Tidvis gjør kapasitetsproblemer det vanskelig for sentralen å opprettholde ett godt servicenivå. Dersom sterilsentralen sitt prosessdesign ikke er godt nok gjennomtenkt, kan den risikere å bli en begrensende faktor for sykehusets primærfunksjoner.

Denne masteroppgaven skal derfor undersøke hvilke avgjørelser det er viktig å ta i forbindelse med å bestemme sterilsentralens prosessdesign. For å ta slike designavgjørelser med ett godt nok beslutningsgrunnlag vil det være viktig å ha tilgang på den nødvendige informasjonen til riktig tid. Oppgaven skal derfor videre undersøke hvordan en systematisk designprosedyre kan være med på å tilrettelegge for dette, og for design av sterilsentraler som er godt egnet for å møte fremtidens etterspørsel. Det overordnede forskningsmålet for oppgaven er derfor å bidra til å planlegge sterilsentraler fra innsiden og ut, slik at en kan prioritere å legge til rette for funksjonene på sterilsentralen når strategiske designavgjørelser skal tas. For å nå dette målet, ble følgende forskningsspørsmål besvart i oppgaven:

1) Hva er viktige designavgjørelser en må ta i prosessen med å designe en sterilsentral?
2) Hvordan kan en mer systematisk designprosedyre legge til rette for design av sterilsentraler som er godt egnet for å møte fremtidens etterspørsel?

Forskningsdesignet brukt i masteroppgaven består i en kombinasjon av en litteraturstudie og to casestudier. Basert på funn fra litteratur og casestudiene er strategiske og operasjonelle design-avgjørelser i forbindelse med planleggingen av prosessdesignet på sterilsentralen blitt identifisert. De strategiske avgjørelsene omhandler plassering, layout, langsiktige krav til

størrelse og kapasitet, samt tilrettelegging for miljøkravene som er tilstede på sterilsentralen. De operasjonelle avgjørelsene er relatert til valg av servicedesign, teknologi, samt organiseringen av de ansatte og deres arbeidsoppgaver. Disse avgjørelsene har vist seg å være tett knyttet, og under påvirkning fra flere eksterne og interne faktorer. Det vil med andre ord kreve mye innsikt og kunnskapsrike sykehusplanleggere for å kunne ta slike avgjørelser. Designprosessen kan beskrives som iterativ og spesielt utfordrende når rett informasjon ikke er tilgjengelig til rett tid, for å støtte beslutningene når de må tas. Det er grunn til å tro at bruke av en systematisk designprosedyre for å koordinere prosessen med å designe sterilsentralen kan være en fordelaktig, både for planleggerne og det resulterende designet. En slik prosedyre eksisterer ikke i dag, verken i litteratur eller i praksis.

Denne oppgaven bidrar med et forslag til en seks-trinns systematisk designprosedyre for prosessdesign av sterilsentralen. En slik prosedyre kan bidra til å koordinere de ulike aktørene involvert i designprosessen. Den gir god oversikt over hvilken informasjon som må være på plass før viktige designavgjørelser blir tatt. Tilrettelegging for en tidligere enighet og forståelse av målene, funksjonene og kapasitetsbehovet i sterilsentraldesignet kan være avgjørende for sluttresultatene. Det kan også være viktig input når areal skal tilegnes sterilsentralen. Dette vil være med på å tilrettelegge for en sterilsentral som er planlagt fra innsiden og ut, med funksjonalitet som første prioritet når viktige strategiske beslutninger blir tatt.

Hvor godt egnet designene vil være å møte fremtidens krav vil i stor grad avhenge av kvaliteten på analysene, prognosene og input-informasjonen brukt i planleggingsprosessen. En systematisk designprosedyre vil være med på å gi beslutningstakere de beste forutsetningene for å designe sterilsentraler godt rustet for å møte fremtidens etterspørsel.

Acknowledgement

This master thesis is submitted as the final work of the Master of Science program in Mechanical Engineering at the Department of Mechanical and Industrial Engineering at NTNU

The thesis investigates the process design of the Central Sterile Processing Department in an hospital. It examines important design decisions to be made in the process of designing the CSPD, and how a systematic design procedure can facilitate for informed decision-making, and designs that meets the future requirements. The interest on the topic has been great both from the staff concerned with the operations of the sterile departments, and from the hospital planners involved with the process of making the important design decisions. The study aims to fill a void in literature and practice.

I would like to thank my supervisor Jan Ola Strandhagen for valuable guidance and constructive feedback. I also would like to thank my co-supervisor Giuseppe Fragapane for his encouragement, guidance and for being available when needed. In addition, I would like to thank Bjørn Bakken at Sykehusbygg HF for providing real life insight into the topic of designing sterile departments and for arranging contact with the case hospitals. I would like to thank Stian Refsnes Henriksen and the dedicated project group of "SUS2023" at Stavanger University Hospital for their interest in my project and for their willingness to share necessary insight. Lastly, I would like to thank CSPD manager Anne Margrethe Berg and her colleagues at St. Olav University Hospital for their participation and valuable insight into the topic of the thesis.

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Elise Keseler

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Abbreviations and Acronyms

CSPD – Central Sterile Processing Department

SPD – Sterile Processing Department

ER – Emergency Room

ICU – Intensive Care Unit

OR – Operating Room

WIP – Work in process

ICT – information and communication technology

IT – Information technology

AGV – Automated Guided Vehicle

RFID – Radio Frequency Identification

HF – "Helseforetak"

PPE - Personal Protective Equipment

ERP – Enterprise Resource Planning

SLP – Systematic layout planning

1. Introduction

The introduction presents the background and motivation of the thesis. A problem description is provided, as well as a presentation of the research questions and objectives. The scope of the thesis will be narrowed down and explained. Lastly, an overview of the thesis content will be given.

1.1 Background

Sterile processing logistics are among the supporting processes that have been recognized to have a great impact on the overall efficiency of a health care system (Di Mascolo & Gouin, 2013). It is comprised of activities that are both cost- and labour-intensive, and therefore incurs a high opportunity cost for many hospitals (Di Mascolo & Gouin, 2013; van de Klundert, Muls, & Schadd, 2008).

The hospitals are struggling with having to become more and more efficient, whilst at the same time experiencing an increased economic pressure to cut costs (Di Mascolo & Gouin, 2013). It is recognized that cost reductions in the secondary processes of the hospital can help free money to the primary care processes of the hospital (van de Klundert et al., 2008). As a consequence, there has been given increased attention to improving the sterile processing logistics the last decade (Di Mascolo & Gouin, 2013; van de Klundert et al., 2008).

Sterile logistics is considered as a highly ranked hospital logistics field (Kriegel, Jehle, Dieck, & Mallory, 2013). The sterile processing function of an hospital can be compared to the function of the technicians maintaining the landing gear of a plane (Jackson, 2006), and the pilot will be the surgeon. It is the responsibility of the pilot to land the plane, but there will not be a successful landing unless the landing gear is in the required shape. Hence, the sterilization of medical devices is an essential and indispensable support activity in any health care facility (Di Mascolo & Gouin, 2013; Swenson, 2013b). The consequences of utilizing contaminated medical devices in patient treatment can be severe and lead to serious complications (McDonnell & Sheard, 2012). The consequence of poor sterile logistics may also endanger patient health, seeing as patient safety is directly linked to the logistics of having the required equipment available when needed (Chobin & Swanson, 2012; van de Klundert et al., 2008). The task of the Central Sterile Processing Department is to provide the required trays of

instruments, in the required condition, at a rate that supports the operation schedule and procedures of the hospital (Lin et al., 2008).

Sterilization has evolved a lot over the recent years. From a decentralized service performed in the annex of the operating room by the operating nurses, towards an centralized activity where larger scale sterilization is performed in a separate department by specialized technicians (Di Mascolo & Gouin, 2013). The centralization of the sterile supply function has made it possible to apply production techniques to the processes and strive towards optimizing the workflows (Allen, 1976). According to (McDonnell & Sheard, 2012) a correctly designed CSPD is the first step towards ensuring patient safety. They emphasise how careful consideration must be given to designing an appropriate layout and workflow in sterile processing facilities, seeing as it is too often the case that the departments are found to be inadequate.

The aim of process design is to make sure that the process will perform accordingly to the objectives it seeks to achieve (Slack, 2013). The main objectives of sterile processing is to provide the customers with 100% clean and sterile instruments, 100% complete instrument trays, delivered 100% on time (Johnson, 2005). The stakes of not achieving this in a hospital setting can be terrifyingly high.

This thesis will investigate important design decisions that must be taken in the process of designing a Central Sterile processing department and implications on how the design procedure can be improved. By combining literature and real-life case studies, the aim is to contribute with guidance to the decisionmakers in charge of designing the processes at the Central Sterile Processing Department.

1.2 Problem Description

Like many areas of the hospital, the Central Sterile Processing Department (CSPD) often struggles with capacity issues (Dziwis, 2010). The changing demographics of the populations, in addition with the rapid medical evolvement, results in increased volume and variation of medical procedures carried out in the hospital (Strunk, Ginsburg, & Banker, 2006; Sykehusbygg, 2017). This does not go by unnoticed in the CSPD, which is the engine that drives the surgery department (Dziwis, 2010; Swenson, 2013b). The CSPD is under high pressure, and the efficiency requirements are increasing. Inorder to accommodate the increased pressure and tackle the capacity issues, there may be need for increasing the workforces, as well as rennovation or reorganization of the Sterile departments. In some cases an entirely new department might be the best solution (Swenson, 2013b).

Whether the goal is to renovate or build entirely new, both scenarios provide an opportunity for designing a state-of-the art processing department that facilitates services of high quality and optimal efficiency. In order to accomplish this, planning is key (Chobin, 2001). The final process design should be constructed to improve the physical layout, workflow and staff productivity (Chobin, 2001). Building or renovating is expensive and often an inconvenience for the hospital, hence the opportunity to do so does not present itself often. When it does, it is of great importance to design a department that is functional today, and at least couple of decades ahead in time (Chobin, 2001). The strategic decisions of the process design have strong implications for the operational performance of the CSPD. If not designed and planned correctly the CSPD could end up being a limiting resource within the hosptial (Dziwis, 2010). Understanding and optimizing the processes at this department is therefore of great importance, and it all begins with the process design.

This thesis is initiated in cooperation with Sykehusbygg HF. Sykehusbygg HF is a state-owned company involved in the planning, designing and construction of Norwegian hospitals. Their work includes planning and designing sterile processing departments and the accompanying logistics loop. Designing the CSPD has shown to be a knowledge-intensive and complex task, that requires greater decision support.

The purpose of the thesis is therefore to serve as a starting point for providing better decision support for the decisionmakers that are planning the CSPD. It will investigate what the important design decision related to planning the CSPD are. In order to make these decisions at the right time and with the right input information, the thesis will also investigate how a systematic procedure for designing the CSPD could benefit the end results. The overall research goal is to help facilitate for planning the process design of the CSPD from the inside and out, so that the functionality of the sterile department can be made a priority when strategic decisions are being made.

In order to do so, the following research questions will be answered in this thesis:

RQ1: *What are the design decisions involved when designing the processes of a Central Sterile Processing department?*

RQ2: *How can a systematic design procedure facilitate for CSPD designs that meet the future requirements?*

1.3 Research Scope

The scope of the thesis is placed within is Hospital logistics. Hospital logistics can be defined as the processes involved in "the complex task of ensuring that the necessary resources and production factors are available at the point of care in hospitals" (Kriegel et al., 2013). The processes referred to is typically "purchasing, materials planning and scheduling, inventory control, material handling and physical distribution of medical supplies, and supporting services" (Rossetti, Buyurgan, & Pohl, 2012).

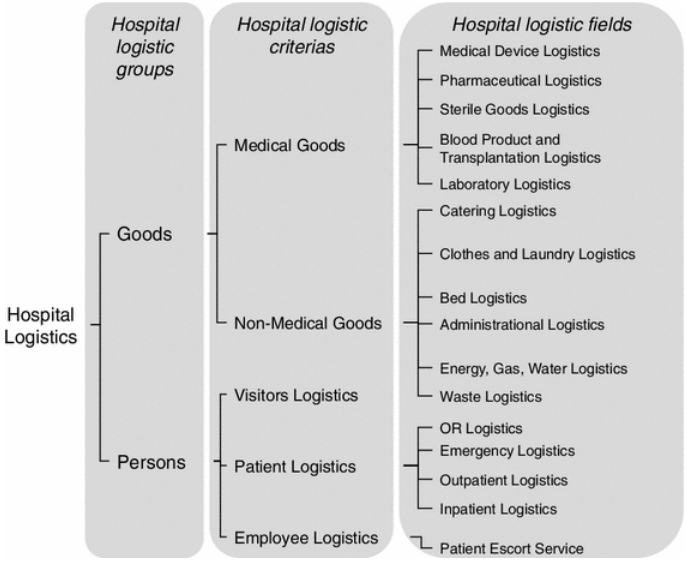

Figure 1: Hospital logistics, adopted from (Kriegel et al., 2013)

The focus of the thesis will be on the Sterile goods logistics, which is one of the hospital logistics fields that can be seen in Figure 1. Sterile medical goods are often classified as either single-use items or reusable equipment, these are further explained in Chapter 3.2.1 (Ozturk, Begen, & Zaric, 2014; Volland, Filgener, Schoenfelder, & Brunner, 2017). The scope of the thesis is mainly concerned with the processes involved in supply and reprocessing of reusable equipment, seeing as this is the main task of the CSPD. The reusable equipment is designed for reuse and usually move in a loop between being utilized in patient care and sterilized in the sterile processing department (Volland et al., 2017). The science of the sterilization methods is excluded from the scope.

The sterile supply function of a hospital may have several configurations. It can be performed either decentralized or centralized, in-house or outsourced. The configuration considered in this thesis will be the in-house and centralized Sterile processing department. This is due to its state as the trending configuration in Norwegian hospitals. The study will however be applicable to

the outsourced configuration as well, the processes are the same, expect for the external shipping distances between the CSPD and the hospital that comes with outsourcing.

The CSPDs ability to provide successful services is highly influenced by its process design. In operations management process design is defined as "the overall configuration of a process that determines the sequence of activities and the flow of transformed resources between them" (Slack, 2013). Design decisions are defined as "the decisions that affects the physical shape or nature of the processes" (Slack, 2013). To limit the scope, the design decisions to be considered will be the once related to the design activities in Figure 2, with emphasis on the strategical design activities. The strategic decisions can however not be seen independently from the operational process design activities, seeing as the strategical activities have great implications for the operational, and vice versa (Slack, 2013). Therefore, the influence of the operational design activities will also be included. The scope is quite broad, to capture the complex nature of designing the CSPD.

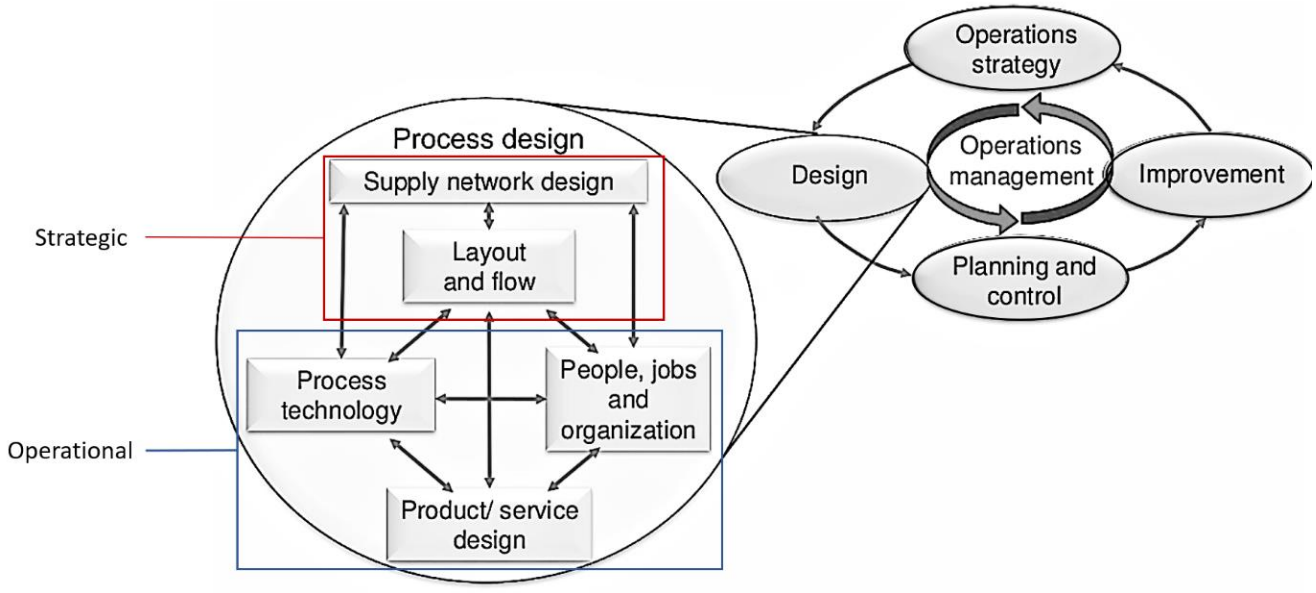

Figure 2: The design activities in Operations Management(Slack, 2013)

1.4 Thesis Content

Table 1: Thesis Content

Chapter 1 Introduction	The Introduction provides the reader with background information to motivates the thesis, a problem description that provides the research questions, the thesis scope and a description of the thesis structure.
Chapter 2 Research Methodology	The Research Methodology provides the reader with the research methodology applied in the thesis, and insight into why the chosen methodology was applied.
Chapter 3 Theoretical Background	The Theoretical Background presents the reader with the necessary background information to understand the topics of the thesis scope. The literature consists in general theory on process design, recent research on the topic of Sterile goods logistics and process design.
Chapter 4 Empirical Background	The Empirical background provides the reader with the empirical background and information collected through the two case studies of the thesis. The first case is concerned with designing the new CSPD at Stavanger University Hospital. The second case study provides insight into the operational aspect of the CSPD at St. Olav University Hospital, and how it is affected by its current process design.
Chapter 5 Findings & Discussion	The Findings & discussion provides the reader with the findings and discussion related to each research question, based on the discoveries from Chapter 3 & 4. A contribution to generalizing the findings is provided through the identified design decisions and a suggested systematic design procedure for the process design of the CSPD.
Chapter 6 Conclusion	The conclusion provides the reader with concluding remarks on how the research questions have been answered through this thesis. Limitations of the study and topics of interest for further research is also presented.

2. Research Methodology

In this chapter the research methodology applied to answer the research questions of the thesis will be presented. Chapter 2.1 provides the methodology of the literature study and Chapter 2.2 the methodology for the empirical data collection in the case studies.

"Research is a process of steps used to collect and analyse information to increase our understanding of a topic or issue" (Creswell, 2012). The research approach applied to address the research questions in this thesis is qualitative. A qualitative research approach was chosen due to the fact that qualitative research is best suited for research problems related to a real life phenomenon, in which you do not know the variables and there is a need to explore and understand the complexity and nature of the phenomenon.(Creswell, 2012; Leedy, 2012).

The methodology applied consists in a literature study and empirical data collection through two case studies and expert interviews. As often seen in qualitative studies, triangulation is applied. Triangulation refers to the use of different methods to collect data about the same phenomenon (Patton, 1999). It is the process of corroborating evidence from different individuals and different types of data, such as theory, interviews, observations, documents and field notes (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014; Creswell, 2012). The logic behind applying triangulation is that using several methods to view the same phenomenon will increase the validity of the results (Patton, 1999).

The theoretical background presented in Chapter 3, is based on findings from the literature study. The case studies were used to gather the empirical data, which is presented in Chapter 4. The combination of information gathered through the literature study and the empirical findings, forms the basis for the findings & discussion in Chapter 5 .

2.1 Literature study

In order to examine the state of the art within the topics introduced in the scope, a literature study was conducted. The literature study introduces relevant terminology, current research and general theory. The literature study provides the necessary theoretical background for answering the research questions.

The literature study was carried out in several steps. The first step was to conduct random and explorative searches on broad topics such as “hospital logistics”, “Sterile processing department” or “Sterilization logistics”. These searches led to a general overview of different thematic, research areas and the vocabulary used. Once the thesis scope became narrower, the searches were more specific. Building block searches was conducted in order to find topic-specific articles. The search words were combined with Boolean operators, such as “Sterile processing” + “Hospital” or “Design” + “Central sterile processing department”. A selection of search combinations can be seen in Table 2. Cited reference searches were also utilized. That is when a key article is identified and used to look for other relevant articles.

Table 2: Building block searches

Block 1	**Block 2**
Sterilization	Design
Sterile logistics	Process Design
Sterile processing	Configuration
Sterile supply logistics	Transportation
Sterile supply network	Inventory
Central Sterile processing department	Layout
Central sterile service department	Technology
Sterile supply loop	Staff

The information provided through the literature study has been drawn from several different sources of information. For definitions and the basic theory on topics such as operations management and process design the information was mostly retrieved from textbooks such as (Slack, 2013) and (Stevenson, 2014). When it came to basic theory and definitions on sterile processing, textbooks like (McDonnell & Sheard, 2012) and (Kobus, 2008) were utilized.

In order to look for articles to provide more in-depth information on current research and problematic within the field, the following databases were utilized: Web of Science, Google Scholar, Scopus, and NTNU University Library (Oria), ProQuest and PubMed. The results from the searches led to articles and literature with varying relevance and context.

Some of the literature were peer-reviewed journal articles and literature reviews written by scientific researches. While other streams of literature were papers and articles published by practitioners on the inside and outside of the CSPD, discussing observations and current issues. Additionally, some secondary information was retrieved from the websites of the case hospitals in questions.

When conducting the searches, the literature was first evaluated according to relevance and quality. The degree of relevance was decided by the title and reading the abstract or introduction. If the content categorized as relevant, further reading was conducted. The articles were also evaluated based on how current the research was, with the intention of including mainly current research. The articles included in the literature study are written in English and the focus has been to include mostly academic or scientific articles and journals. To manage the references and citations the software EndNote was utilized, in combination with Microsoft word.

2.2 Empirical data collection

The empirical data of the thesis consists in the information collected through two case studies, which are presented in Chapter 4. Observations, semi-structured interviews and document collection contribute to the empirical background. In addition to the two case studies, insight and validation have been provided through meetings and discussions with Sykehusbygg HF during the process of writing the thesis.

Many definitions are available for the case study. (Yin, 1984) explains it as "An empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are used." Case studies are applicable for different research purposes. Some strengths of the case study approach is the advantage of observing how the phenomenon works in its natural setting, do exploratory investigations and to answer why, what and how questions (Benbasat, Goldstein, & Mead, 1987). Another major strength of the use of case study data collection, is the opportunity to use different sources of evidence to strengthen your findings (Yin, 2011).

In this thesis two case studies are conducted. The cases are used to gain insight and in-depth understanding of the processes at a sterile processing department and how their performance is connected to the process design. The cases and interviewees were purposefully chosen with the intention to gain insight from participants with different perspective and insight into the

phenomenon. The research term for this qualitative approach is defined by (Creswell, 2012) as purposeful sampling. Bjørn Bakken from Sykehusbygg HF served as a "gatekeeper" in the thesis, by assisting the researcher in the process of identifying relevant cases to study and people to interview (Creswell, 2012).

The two cases were chosen to provide different insight into the thesis topic. The first case is concerned with the collecting the strategical and operational views on designing the new CSPD at Stavanger University Hospital. The second case study provides insight to the operational aspect of the CSPD at St. Olav University Hospital, and how it is affected by its current process design. Multiple types of information were collected and added to the study during the research period. Observations, Semi-structured interviews, documents, visual material and audio material was collected through the case studies

Semi-structured interviews

Multiple semi-structured interviews were conducted. The purpose was to interview key personnel with the possibility to provide solid intel to the processes of operating and designing the CSPD. The interview participants have been both managers, section leaders and personnel involved with the day-to-day operations of the sterile department. But also, strategical planners involved in the complex process of planning the design, layout and workflow of the CSPD. The reason behind including both an operational and strategical point of view, is because the strategical decisions of the process design have strong implications for the operations at the CSPD. Through the interviews a more detailed understanding was developed, interesting insight and viewpoints were provided, and it gave a voice to several central stakeholders of the CSPD. The interviewees that have contributed to the master thesis are listed in Table 3.

A semi-structured interview is a flexible interview technique consisting in a set of predefined questions, answered through an unstructured interview allowing for open-ended exploration and deflection from the predefined questions (Wilson, 2013). In preparation of the interviews an interview guide was constructed, to scope down the purpose and topics to be covered in each interview, as well as suggested follow-up questions. The interview guides were adapted to match the background and ability of the informants. Before the trip to Stavanger University Hospital the interviewees were provided with the interview guide, this was to make sure that the topics were covered within the given timeframe of the trip. During the interviews most of the topics were covered and additional information collected. Semi-structured interviews proved as an effective way to collect data and at the same time confirm or reject thoughts from

observation. The interviews were carried face-to-face and in Norwegian. With the consent of the participants, audio recording was used to capture all the information of the interviews. The audio-recordings were later transcribed on computer, into reports with the information retrieved from each interview.

Table 3: Overview of case study interviewees

Location	Interviewee	Job position	View
St. Olav Hospital	Ann Margrethe Berg	Department Manager, CSPD	Operational
St. Olav Hospital	Randi Solheim	Section Manager, CSPD	Operational
St. Olav Hospital	Jo Willy Gråwe	Quality Coordinator	Operational
Sykehusbygg HF	Bjørn Bakken	Hospital logistics planner "Fagansvarlig logistikk"	Strategical
Sykehusbygg HF	Vincent Maure	Hospital planner "Rådgiver Spesialrom"	Strategical
Stavanger University Hospital	Kristin Gjertsen	Department Manager, SPD	Operational
Stavanger University Hospital	Ove Nordstokke	Project Manager of the CSPD, SUS2023	Strategical
Stavanger University Hospital	Anne Underhaug	Project Architect of CSPD, SUS2023	Strategical
Stavanger University Hospital	Stian Refsnes Henriksen	Logistics manager of CSPD, SUS2023	Strategical

Observations

Observations were carried out both in the current Sterile department in Stavanger University and the CSPD at St. Olav University Hospital. Observing is an method of gathering open-ended and first-hand information by observing the people and processes at a research site(Creswell, 2012). The observation helped understanding the process and get a general sense of the sites. An advantage of observing is the opportunity to observe the processes in a natural setting and study actual behaviour that may not be easy to verbalize, such as the complex processes inside the sterile department (Creswell, 2012). The observations are however limited to the two sites the researcher was able to gain access to.

Secondary Data

Relevant and semi-relevant information were also gathered through documents, illustrations and rapports provided by participants in meeting and interviews. Documents provide a good source for text data in a qualitative study, and there has often been given thoughtful attention to writing them (Creswell, 2012). St. Olav Hospital provided the researcher with a thorough flow chart for material and information flow throughout the sterile logistics loop in the hospital, as well as illustrations of the layout in the CSPD. Stavanger Hospital provided drawings of the preliminary and current design of the sterile functions, logistics notes and power points related to the project. Sykehusbygg HF have also participated in providing diverse documents of interest as well as informative meetings.

Analysing and interpreting the Empirical data

Once the empirical data is collected the next, and important step, is to analyse and interpret the body of information gathered. The data analysis approach used in this thesis is well explained by (Creswell, 2007); First, the data are organized and arranged in a logical order. The data is skimmed through several times to get a grip of the content as an entirety. This allows for splitting the text up in sections and interpreting the information, before it is clustered into meaningful categories. The data is then scrutinized for patterns and compared to the literature findings in order to see if any generalization can be applied to the conclusions drawn, to make the studies applicable for other instances than the exact cases that has been studied. The analytic approach resulted in both providing detailed case descriptions, setting the case within its contextual conditions, and presenting the findings in a sensible manner. As done in chapter 4 and 5.

Validation of findings

In the process of collecting data and analysing it, it is important to validate that the findings and interpretations are accurate (Creswell, 2012). As mentioned in the introduction in Chapter 2, triangulation is applied to increase the validity and accuracy of the findings in the thesis. Triangulation is a validity procedure in which information is collected from several information sources, individuals and processes. By doing so, the researcher is encouraged in providing an end result that is both accurate and credible (Creswell, 2012). Another means for providing valid findings is close collaboration with participants, were the participants are involved in providing additional information where uncertainty is present (Creswell & Miller, 2000). In addition to collaboration and validation through emails, Bjørn Bakken at Sykehusbygg HF have

also provided peer debriefing at early stages in the process. The debriefings provided support and discussions on the topic understanding and interpretations made by the researcher.

3. Theoretical Background

This chapter presents the state of the art within the topics included in the thesis scope. It serves as important theoretical background for answering the research questions. Chapter 3.1 provides the reader with general theory on process design. Chapter 3.2 provides an overview of the sterile medical goods supply and its related logistics. A thorough explanation is given of the Central Sterile Processing department and its processes. Chapter 3.3 presents the literature related to designing the CSPD.

3.1 Process design

This chapter will provide the basic theory about process design in operations management. It is divided into chapters based on the different design activities involved in process design. Chapter 3.1.1 provides theory on Supply Network design, chapter 3.1.2 on Layout and flow, chapter 3.1.3 on process technology, chapter 3.1.4 on people, jobs and organization and 3.1.5 on product and service design. While chapter 3.1.6 provides relevant tools and theories for process design gathered from literature.

There exists several definitions of what a process is, (Stevenson, 2014) provides us with one; "A process is one or more actions that transforms inputs into outputs." While (Slack, 2013) provides us with another; " A process is an arrangement of resources that produces some mixture of products and services." Design in defined by (Slack, 2013) as "The activity of determining the physical form, shape and composition of operations and processes". Process design is defined as "The overall configuration of a process that determines the sequence of activities and the flow of transformed resources between the" (Slack, 2013) .The purpose of the process design is to achieve the required levels of quality, flexibility, speed, dependability and cost in order to meet the customer needs (Slack, 2013).

In operations management decision making is commonly divided into strategical, tactical and operational decisions, which all have implications on the process performance. The biggest difference between them are the time-horizons. Strategical decisions are concerned with long-term decisions such as location, facility capacity, the relative configuration of activities and actors, as well as physical and functional design. While tactical and operational decisions involve more short-term decisions such as planning, scheduling, as well as the management of people, inventory and operational day-to-day processes (Stevenson, 2014). Strategy provides direction and goal, tactic decide the methods and actions to accomplish the goals, while

operations is the actual "doing" part of the process (Stevenson, 2014). Many of the decisions related to the process design are typically strategical decisions that involves long-term commitment. They do however have strong implications for the operation of the processes, seeing as they directly affect many essential parameters such as cost, space, capacity and quality(Stevenson, 2014). (Slack, 2013) describes how process design can be divided into strategical and operational decisions also. Where the process design at a strategic level is concerned with the overall configuration and shaping of the networks and operations that supply the products or services. While at a more operational level process design means organizing the people, technology and operational processes. The design activities involved with process design is illustrated in Figure 3.

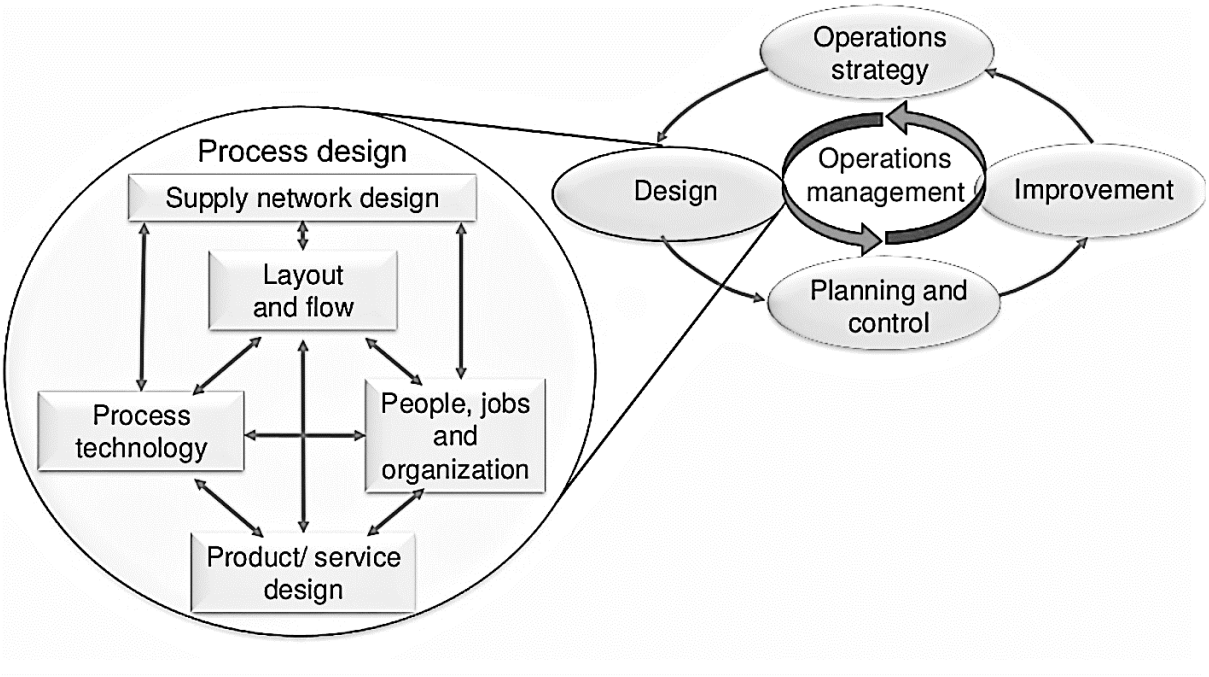

Figure 3: Process design activities, (Slack, 2013)

3.1.1 Supply network design

Designing the supply network design means placing the operation in the context of its interacting operations, such as its suppliers and customers. The supply network view comprises three important strategical design decisions (Slack, 2013). These are

1. *How should the network be configured?*

   This means determining the overall organization and relative arrangement of all the operations that make up a supply network. This configuration can in example change shape if a business chooses to outsource or vertical integrate parts of their operations.

   Outsourcing is defined as the practice of contracting out work that has previously been done within the operation. While vertical integration is choosing to perform a previously outsourced activity in-house (Slack, 2013).

2. *Where should each part of the network be located?*

   The choice of location is important, and it will usually impact the operations cost and the service level they are able to deliver to the customers. The location decision is also challenging to undo, moving location is both expensive and often provides inconvenience for the customers. But when operations do move, it is often due to one out of two reasons; either changes in supply or changes in demand. The location can have significant impact on any operation and affect parameters such as cost or service level (Slack, 2013).

3. *What physical capacity should each part of the network have?*

   The long-term capacity management decisions are concerned with deciding the appropriate size and capacity of each part of a network. It includes identifying the right balance between capacity and demand, and timing potential capacity changes in order to adapt to changes in demand. A helpful tool here is forecasting (Slack, 2013). Forecasts are a basic input in decision processes, because they provide information on future demands on variables of interest. (Stevenson, 2014)

The *capacity* of an operation can be defined as "the maximum level of value-adding activity over a period of time that the process can achieve under normal operation conditions"(Slack, 2013). It is common to distinguish between long-, medium- and short-term capacity decisions. The strategic long-term decisions sets the overall fixed physical capacity of an operation, such as the facility size. Medium- and short-term capacity decisions are concerned with adapting the operational capacity to short term demand fluctuations. The long-term capacity decisions

require forecasting of demand over a longer time horizon, and then converting the forecasts into capacity requirements (Stevenson, 2014). Assessment of long-term capacity needs also includes deciding the degree of flexibility to incorporate. Keeping inventory is a measure that can be taken to facilitate the smoothing of supply and demand, when faced with uncertainty in demand (Slack, 2013).

The *theoretical capacity* of an operation is the capacity the technical designers had in mind when the process design was provided. But the *effective capacity* may not always equal the theoretical, due to real life hiccups such as maintenance, quality issues, machine breakdowns or absent workers (Slack, 2013). (Stevenson, 2014) explains how some key determinants for effective capacity is the design of facilities, including size and the room for expansion. The effective capacity is also influenced by the workforce, and the ability of the workforce to preform effectively is connected to the work design and environmental factors such as heating, lighting and ventilation.

3.1.2 Layout and flow

Layout is referred to as strategic resource organization by (Stevenson, 2014). The layout is concerned with the task-allocation and relative arrangement of the transforming resources of an operation or process. It means deciding where to place resources such as departments, work centres, machines, equipment and staff of the operation. The layout decides how the transformed material flow through the operation (Slack, 2013).

Three reasons why layout decisions are of importance (Stevenson, 2014):

1) A layout requires substantial investments in the shape of money and effort.
2) The layout is a long-term commitment, faulty design may be challenging and expensive to undo.
3) The layout has a significant impact on the cost and efficiency of the operations. Relatively small changes in layout can have large impacts on the costs and general effectiveness of an operation.

An unfit layout can result in confusion, inflexibility, long processing times and customer queues. The best way to avoid these effects is to have a clear vision of the objectives and tasks of the layout before designing it. The objectives of the layout often relates to the strategic objectives of the operation. But generally, a layout should facilitate for safe processing,

minimize flow length and production time, eliminate unnecessary movement, avoid bottlenecks, provide a clearly defined flow, utilize the space and workers in a good way and allow for long-term flexibility (Slack, 2013; Stevenson, 2014). A bottleneck operations is defined by (Stevenson, 2014) as ”an operation in a sequence of operations whose capacity is lower than that of the other operations.” The configuration of layouts come in many shapes. The choice of layout often depends on the volume and variation characteristics of the process.

The four basic layout types are defined by (Slack, 2013):

i) Fixed position layout

Is when the product being transformed or produced is fixed in one place, but the transforming resources move around it. This is often the case when an object is too large or fragile to move, such as a ship or a patient in surgery (Slack, 2013).

ii) Functional layout

In a functional layout similar resources and processes are gathered in departments or functional groupings. The products that are being transformed moves through the process, from activity to activity according to their processing needs. This provides flexibility to handle a wide range of processing requirements but the variation in routes can produce a quite complex flow. An example of a functional layout is a machine shop, it is also quite normal in service environments such as hospitals or universities (Slack, 2013; Stevenson, 2014).

When designing a functional layout there are several details that must be taken into considerations. Some essential pieces of information for the designer is however provided by (Slack, 2013; Stevenson, 2014):

- The area requirements of each work centre and dimensions of the entire facility.
- The shape constraints of the areas allocated to each work centre
- The degree and direction of future flow between the different work centres.
- Special considerations such as whether it is desirable to place certain work centres close together or close to any key utilities.
- The access and exits point, and good receipt in existing buildings.
- The budget

iii) Cell layout

A cell layout is when the transforming resources required to transform similar products are grouped together. Every product in the production have a pre-selected cell where their processing needs are located (Slack, 2013).

iv) Product (line) layout

A product layout locates all transforming resources for the convenience of the products being transformed. The processes are divided into a series of standardized and repetitive tasks to achieve an efficient flow of large volumes of transformed resources. In order to provide a smooth flow with maximum utilization of labour and equipment it is important to balance the flow of work activities. Line balancing is defined by (Stevenson, 2014) as "The process of assigning tasks to workstations in such a way that the workstations have approximately equal time requirements."

U – Shaped layouts: Although a straight production line has its appeal, there are some advantages to be considered with U-shaped layouts. The U-shaped line is more compact, often requires half the length and allows for cross-travel of workers and vehicles, it can facilitate for teamwork by making it easier to communicate. However, if the processes are highly automated or if the operations must be separated due to noise or contamination concerns a U-shape may not be preferable *(Stevenson, 2014).*

Mixed layout: Many processes apply a hybrid layout that combines elements of some of the traditional layout types. In example a hospital is often arranged as a functional layout with its different departments. But the operating rooms within the department may have a fixed-layout, and the X-ray department may be arranged as a functional layout again(Slack, 2013).

3.1.3 Process technology

Technology and technological innovation have had an immense influence on business processes and has become a vital part of any production environment. Technological innovation means "the discovery and development of new or improved products, services, or processes for producing or providing them." While technology refers to "applications of scientific discoveries to the development and improvement of goods and services and/or the processes that produce or provide them" (Stevenson, 2014). Implementing the appropriate technology into the processes can have huge benefits and immensely improve an operations performance. It is however important to understand the capabilities and limitations of the technology, and that

there are risks involved. There are important economic considerations involved with implementing and maintain the technology, the technologies may be demanding to integrate and it will require training and reorganization of the staff involved (Slack, 2013).

(Slack, 2013) distinguishes between three types of processing technology, based on what they process; materials, information or customers. *Material processing technologies* are the technology directly involved with the physical transformation or shaping of products, but also the technology involved with handling, transporting and storing the materials. *Information processing technology*, often called information and communication technology (ICT), comprises any technology that collects, manipulates, stores and shares information. Enhanced availability of information is important input any decision process. The use of internet-based solutions has had a great impact on today's operations. *Customer-processing technology* is comprised of any technology that provides the interface between a process or a service and its customers. There also exists *Integrating technologies* which process more than one type of resource, such as ERP systems in example (Slack, 2013).

Process technology allows for the automation and control of any operation or process. Controlling involves monitoring the system by continuous data collection, where feedback is provided on the state of the system and the personnel can be alerted whenever errors are detected (Slack, 2013). A key question in process design is whether to automate the different processes and to what degree. Automation consists in "machinery that has sensing and control devices that enable it to operate automatically." It offers several advantages over human labour, such as the ability to handle heavy lifts and repetitive work over long time without getting tired, the processing times are predictable and variable costs are reduced. Automation does however come with high initial investments, require standardization and a low degree of variability in processing needs (Slack, 2013; Stevenson, 2014).

3.1.4 People, jobs and organization

Human resources, often referred to as the greatest asset of any operation, is important to consider in process design. Managing the human resources is concerned with many decisions such as; How big should the workforce be and what different skills and capabilities are required? How are the staff going to be organized? How should the tasks be allocated, and the jobs designed? What are the required worktimes and how should they be divided between the staff? These are only some of the basic decisions involved with organizing the people and jobs of an operation.

Job design is concerned with designing the jobs of individuals or groups/teams of employees, allocating worktimes and designing the working environment. A high degree of division and standardization of the labour tasks has both pros and cons. It promotes faster learning and increase the efficiency by reducing non-productive work. On the other side, it provides low degree of work-flexibility, provides monotone working tasks which may impose physical injury to the staff over longer times. The opposite will be job-rotation, which involves rotating the staff between different sets of tasks to provide variety in their jobs. This increases skill flexibility and reduces monotony but is not considered universally beneficial due to the disruptions in both flow of work and the work rhythm of the employees. The nature of jobs vary a lot, some may require high skill flexibility, others high location flexibility and there may also be required flexibility in working hours to meet the imposed demands (Slack, 2013).

Another important aspect is providing ergonomic workplace designs. Ergonomics are concerned with the physiological aspects of job design and how the workers interface with their work environment. It comprises several considerations such as providing safe working environments, that does not exhaust the employees, and provides acceptable levels of noise, temperature and lightning (Slack, 2013).

3.1.5 Product & service design

The process design is strongly connected to the characteristics and design of the product or service that is delivers. It related to translating customer wants and needs into actual products and services (Stevenson, 2014). Services must be designed in a way that can actually be implemented, and products must be designed in a way that allows for its transformation or production (Slack, 2013). This can be explained as the serviceability, which is “the capability of an organization to provide a service at an acceptable cost or profit.” And the manufacturability which entails “The capability of an organization to produce an item at an acceptable profit” (Stevenson, 2014). Innovation is an important activity in service and product design (Slack, 2013).

3.1.6 Tools & Theories

Systematic Layout Planning Procedure

(Muther, 1973) presents us with "a universal approach for systematic layout planning". He describes how the purpose of layout planning is to facilitate the manufacturing process, and to achieve the additional objectives listed below:

- Minimizing material handling, especially travel distance and time
- Maintaining flexibility of arrangement and operation as needs change
- Promoting high turnover of work-in-process – keeping it moving
- Holding down investment in equipment
- Making economical use of floor space
- Promoting effective utilization of labour
- Providing for employees' safety, comfort and convenience

The systematic layout planning (SLP) consists in four important stages illustrated in Figure 4:

Stage 1 – Determine facility location

Take into account: area requirements, area availability, surrounding influences

Stage 2 – Provide overall facility design

Take into account: arrangement of activity-areas and departments

Stage 3 – Determine facility layout design in detail

Take into account: arrangement of the specific machinery and equipment.

Stage 4 – Preparation and Installation

Take into account: design drawings, specifications, implementation and installation.

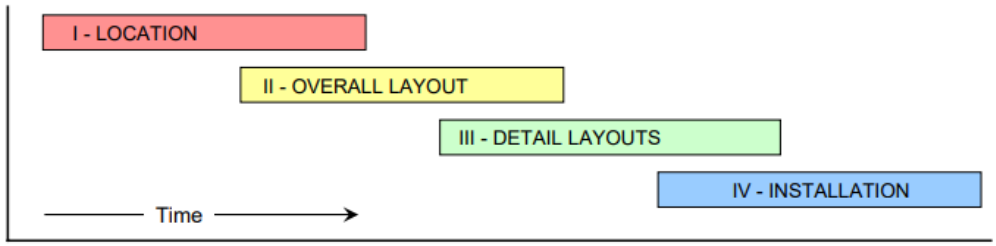

Figure 4: The four stages of SPL

The systematic approach

The planning procedure is a step-by-step procedure that allows for identification, visualization, and rating of the various activities, their relationships in order to develop and evaluate different layout alternatives. The systematic approach is illustrated in Figure 5, and will be briefly explained.

Input Data and Activities:

Some necessary input data must first be collected in a correct manner, and long-term forecasts should be included in the data. These key inputs are:

Products/services	–	*What* is to be produced, processed or distributed.
Quantities/Volume	–	*How much* of each?
Routing/ Process sequence	–	*How* is it processed?
Time	–	*When* and *How long* will items be processed?
Supporting services	–	*With what* support? (people, processes, IT systems)

Analysis:

Once the input data is in place the next steps is to map the relationships between the layout activities and the space requirements in amount and shape for each activity, before adjustments are made in order to provide a layout that facilitates for smooth flow and efficient use of area, with the modifications and limitations that constrain the layout. The details of the process is provided in (Muther, 1973) – Systematic layout planning.

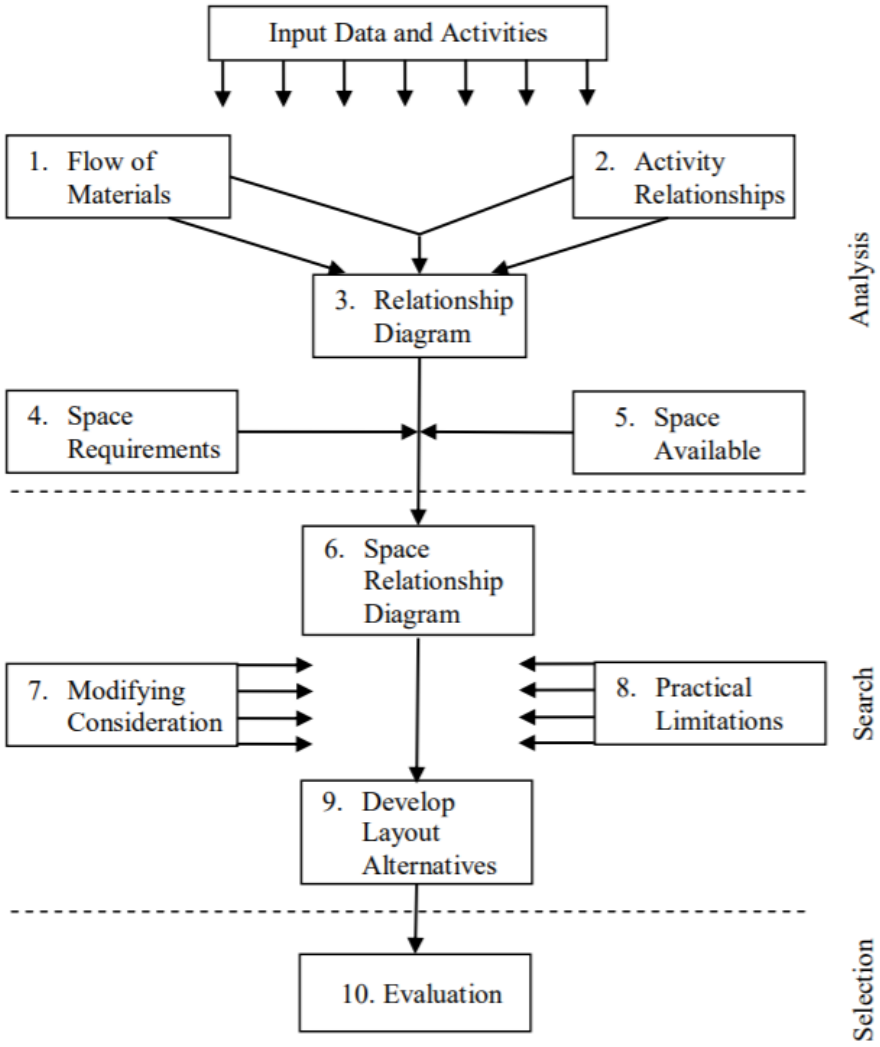

Figure 5: Framework for Systematic Layout Planning

The Contingency Theory

The contingency theory is explained by (Donaldson, 2001) as an organizational theory, which claims that there exists no best way to lead, organize or make decisions in a corporation. This is reasoned by the fact that the optimal course of action in doing so is dependent on several contingencies. These contingencies are explained by (Hayes, 1977) as: the internal factors of a subunit, interdependency factors between different subunits, and the environmental factors that comprises the external interactions the subunit is subject to.

3.2 The Sterile Medical Goods Supply

This chapter provides the theoretical background necessary to understand the processes and logistics of the sterile medical goods supply. The focus will be on the reusable-equipment, which provides the most complex flow. In Chapter 3.2.1 sterile medical goods and their characteristics will be explained Chapter 3.2.2 provides an explanation of the sterile supply logistics in a hospital supply chain and chapter 3.2.3 explains the different configurations the sterile services can have in the supply loop. Chapter 3.2.4 gives an overview of the logistics loop of the reusable sterile equipment internally in the hospital. A thorough explanation of the CSPD and its process design is provided in Chapter 3.2.5.

3.2.1 Sterile medical goods

Among the broad range of supplies necessary for a hospital to perform its core activities are the sterile medical goods. In order to accommodate for the needs of the patientcare procedures, a variety of sterile medical goods are utilized in the hospital's practise every day. Everything from sutures, wound dressings, scalpels and scissors, to complex endoscopic equipment and battery-powered drills (McDonnell & Sheard, 2012).

The medicine of the 21st century offers a wide range of modern treatments to cure the patients by medical or surgical means (McDonnell & Sheard, 2012). The medical and surgical procedures are continuously changing, and with it comes the introduction of new technology and new medical goods. Today, innumerable types of instruments are available to perform the different essential functions in surgery such as cutting, holding, clamping, retracting, observing, draining, injecting, sealing, ligating and measuring (McDonnell & Sheard, 2012).

Medical devices are often classified according to Spaulding's risk scheme, as either non-critical, semi-critical or critical, based on how clean they must be in order to maintain patient safety. The three levels of cleanliness are; clean, disinfected or sterile (Spaulding, 1968). An overview of the classifications and examples of the equipment can be found in Table 4. The requirement depends on several factors such as the type of patient contact the equipment is used for, the degree of contamination they are exposed to and the risk of spreading infection (Chobin & Swanson, 2012; Tvedt-Gundersen, 2016; WHO, 2016).

Table 4: Processing Policy , According to Spaulding's Risk Scheme

Risk category	Recommended level of decontamination	Examples of medical devices
High (critical) Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (semi-critical) Items in contact with mucous membranes or body fluids	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, bedpans, urine bottles
Low (non-critical) Items in contact with intact skin	Cleaning (visibly clean)	Blood pressure cuffs, stethoscopes

The sterile medical goods are often classified as either single-use items or reusable equipment (Ozturk et al., 2014; Volland et al., 2017). The single-use medical items can be defined as a device that has been designed to be used on a single patient and is therefore consumed when used in patient care. Examples are suture trays, implants or urinary catheters. There exists an internationally recognized symbol for single-use sterile items making them easy to identify (McDonnell & Sheard, 2012).

The reusable equipment is however in focus in this thesis. This is medical equipment designed for being used again and again (McDonnell & Sheard, 2012). They have a more complex flow and move in a loop between being utilized in patient care and re-sterilized in the sterile processing department (Volland et al., 2017). Reusable equipment are in many ways preferable to single-use items because reprocessing the equipment saves the hospitals from tons of waste every year (Kwakye, Pronovost, & Makary, 2010). But great attention needs to be given to providing the correct and recommended procedures to ensure safe reprocessing and reuse of the equipment.

All reusable equipment comes with a list of detailed instructions on their reprocessing needs provided by their manufacturer (McDonnell & Sheard, 2012). There are large varieties in the complexity of the equipment. Some are easily cleaned and sterilized as they come, while others require special handling and several steps of dis- and reassembly to be safely sterilized (McDonnell & Sheard, 2012). In order to identify the correct instrument most are marked with labels or some unique identification code, either provided from the manufacturer or by the health care staff (McDonnell & Sheard, 2012).

Most reusable sterile devices are stored and kept in so-called nets (van de Klundert et al., 2008), sets (Ozturk et al., 2014) or trays (Ahmadi, Masel, Metcalf, & Schuller, 2018). These will collectively be referred to as trays in the continuation of this thesis. The trays group the equipment together, often in procedure specific trays, that contains the different items specifically needed for a particular surgery. The trays can also be of a more general nature and to be used in several types of procedures. Often several trays are needed to perform one surgery (van de Klundert et al., 2008). (Chobin & Swanson, 2012) explains how the fleet size of sterile equipment should be based on patient volume and the length of their sterilization process.

3.2.2 Sterile Medical Goods logistics in the Hospital Supply Chain

In general, a supply chain can be defined as "..a network of organizations that are involved, through upstream and downstream linkages, in the processes and activities that produce value in the form of products and services in the hands of the ultimate customer"(Christopher, 2016). This definition is applicable for the hospital supply chain as well. Value is created by facilitating for and providing high quality health care, which is the core activity of the hospital (Polater, Bektas, & Demirdogen, 2014). With the ultimate customer being the patients, nurses or physicians. (Polater et al., 2014) defines the health care supply chain as "a complex system that requires the flow of products, and services in order to satisfy the needs of those who serve patients." Norwegian public hospitals are typical not-for-profit organizations (Slack, 2013), whose primary purpose is not to earn profit. In comparison to a profit-driven organization, the strategic objectives for non-profit organizations often are more complex and characterized by conflicts of interest with regards to political, social, economic and environmental aspects (Slack, 2013).

It is common practice to distinguish between the hospital-external and hospital-internal supply chain (Volland et al., 2017). The external supply chain consists in the processes and distribution activities upstream of the Hospital. The number of actors involved vary, but it usually includes a wide range of vendors, manufacturers and distributors, often in the form of a central warehouse and central pharmacy. Once the supplies arrive at the goods reception at the hospital, they enter the hospital-internal supply chain. The distribution of goods from the goods reception and to their final point-of-use or inventory is a complex chain in itself, and much more than just a link in the supply chain (Landry & Beaulieu, 2007). Traditionally, the hospital goods distribution is designed as a multi-echelon inventory system, as can be seen in Figure 6.

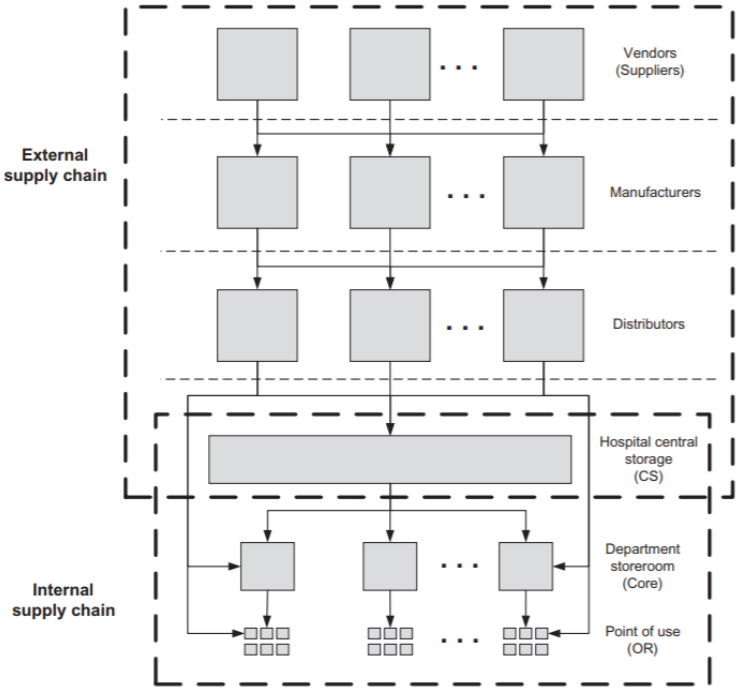

Figure 6: The Hospital Supply Chain (Beaulieu, Landry, & Rivard-Royer, 2002)

The successful fulfilment of the hospitals core activities is highly dependent of the supply of a wide range of products and supporting activities (Moons, Waeyenbergh, & Pintelon, 2019; Polater et al., 2014). Among the main material flows in the hospital supply chain are medical consumables, pharmaceuticals, laundry, waste, catering flows and sterile medical goods (Benzidia, Ageron, Bentahar, & Husson, 2018).

(Kriegel et al., 2013) explains how the sterile goods supply is a highly ranked hospital logistics field. In their study 16 different hospital logistics flows have been identified and prioritized by 120 management-level decisions makers in German Hospitals. Sterile goods logistics is rated as the 4th priority, along with pharmaceutical logistics. The only logistics flow higher prioritized is energy, gas & water logistics, operation room logistics and emergency logistics.

The process of sterilization in the SPD is an essential and indispensable support activity in any hospital supply chain (Di Mascolo & Gouin, 2013; Swenson, 2013b). It is a patient related supporting activity, meaning that the quality and safety of the patientcare in a hospital is directly linked to the sterile goods logistics (Chobin & Swanson, 2012; Kriegel et al., 2013; van de Klundert et al., 2008).

3.2.3 Configuration of the SPD in the Hospital Supply Chain

The organizational configuration of the sterile supply is a field which has been given more attention in literature the recent years, especially when it comes to centralization and outsourcing of the sterile services (Volland et al., 2017). (Di Mascolo & Gouin, 2013) explain how the evolution of standards and regulation in sterilization have changed the nature of sterilization from the simple use of a sterilizing machine, to a complex process of sterilization. This evolution has had consequences for the configuration of the sterile functions in the hospital supply chain. Some years ago, the sterilization activity used to be performed decentralized and fragmented, close to or in the operating rooms of the hospital. Today however, most modern hospitals have reorganized their sterilization function as a separate and centralized service that serves all the hospitals departments (Allen, 1976; Di Mascolo & Gouin, 2013). Centralizing the services allowed for better standardization and quality of the processes, cost reductions, as well as a pooling of both resources and expertise (Giarraputo, 1990).

The centralized sterile processing is carried out in so-called Central Sterile Processing Departments . The CSPD can either be configured in-house, as a part of the internal hospital supply chain, or it can be outsourced to become a part of the external hospital supply chain. (van de Klundert et al., 2008) explain how many health facilities are choosing to outsource the sterilization activities in order to free space, save costs and exploit expert competency in the area. They do however emphasise that outsourcing and changing the logistics principles of the sterile services comes with a risk of lowering item availability and increasing the cost, instead of having the opposite effect. They argue that the cost-effectiveness will depend on the extent the operations and logistics design are optimized. (Moons et al., 2019) discusses how the decision of having an in-house or outsourced CSPD depends on factors such as the interaction between transportation, storage and instrument unit cost. An illustration of the sterilization cycle with an outsourced sterilization service is provided by (Saif & Elhedhli, 2019) in Figure 7.

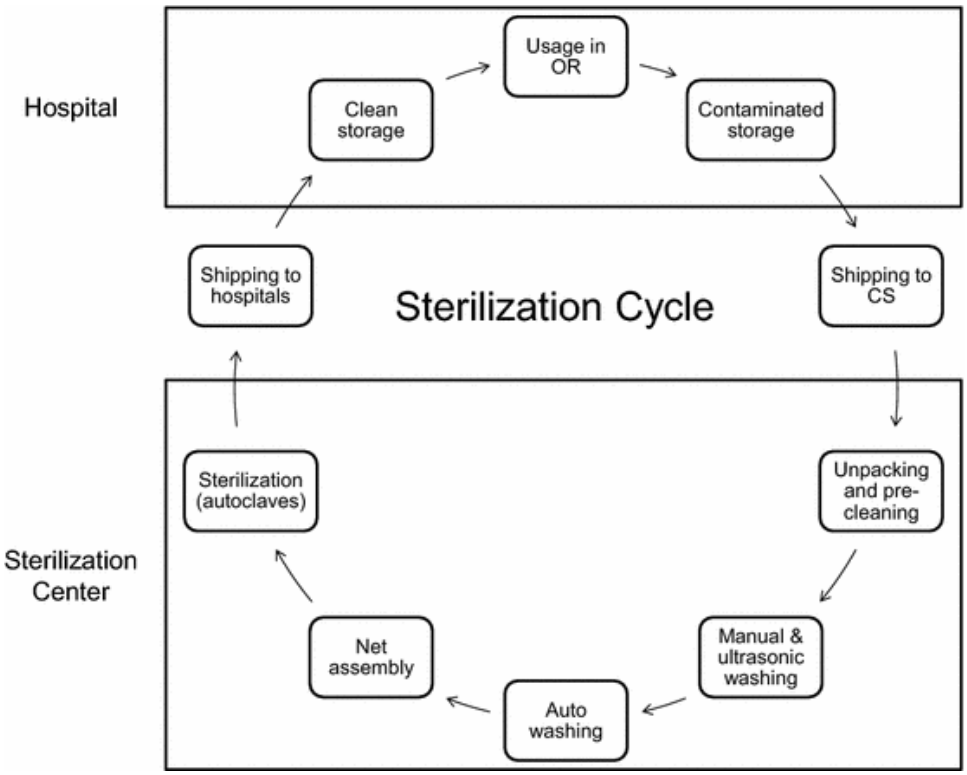

Figure 7: The sterilization cycle with outsourced CSPD. (Saif & Elhedhli, 2019)

(Tlahig, Jebali, Bouchriha, & Ladet, 2013) introduce another outsourcing configuration; a collective and centralized sterilization function that serves a network of hospitals. The formation of such networks has increased in Europe and USA the last two decades. This network configuration could contribute to better utilization of resources and cost savings due to the advantage of operating with economies of scale. However, in order to reap the benefits of such an organization a high level of management is required to ensure equipment availability and satisfactory coordination across the network. (Saif & Elhedhli, 2019) also studies the centralized sterilization network design of a group of hospitals and concludes that implied benefits are improved resource utilization and economies of scale. A prediction for the future is provided by (Kriegel et al., 2013), whom explains that the trends are moving in the direction where more and more patient-related and logistic priority fields, such as sterile logistics are being outsourced.

3.2.4 The logistics loop of the Reusable Sterile Equipment

Patient safety is directly linked to the quality of the sterile processing, but also to the logistics management that ensure the availability of required equipment (Chobin & Swanson, 2012; van de Klundert et al., 2008). The logistics loop of the reusable sterile equipment can be considered as a reverse logistics flow (Moons et al., 2019). It consists in four main activities; storage, distribution, utilization and the reprocessing performed in the CSPD. (WHO, 2016) provides an illustration of all processes involved in the logistics loop in Figure 8.

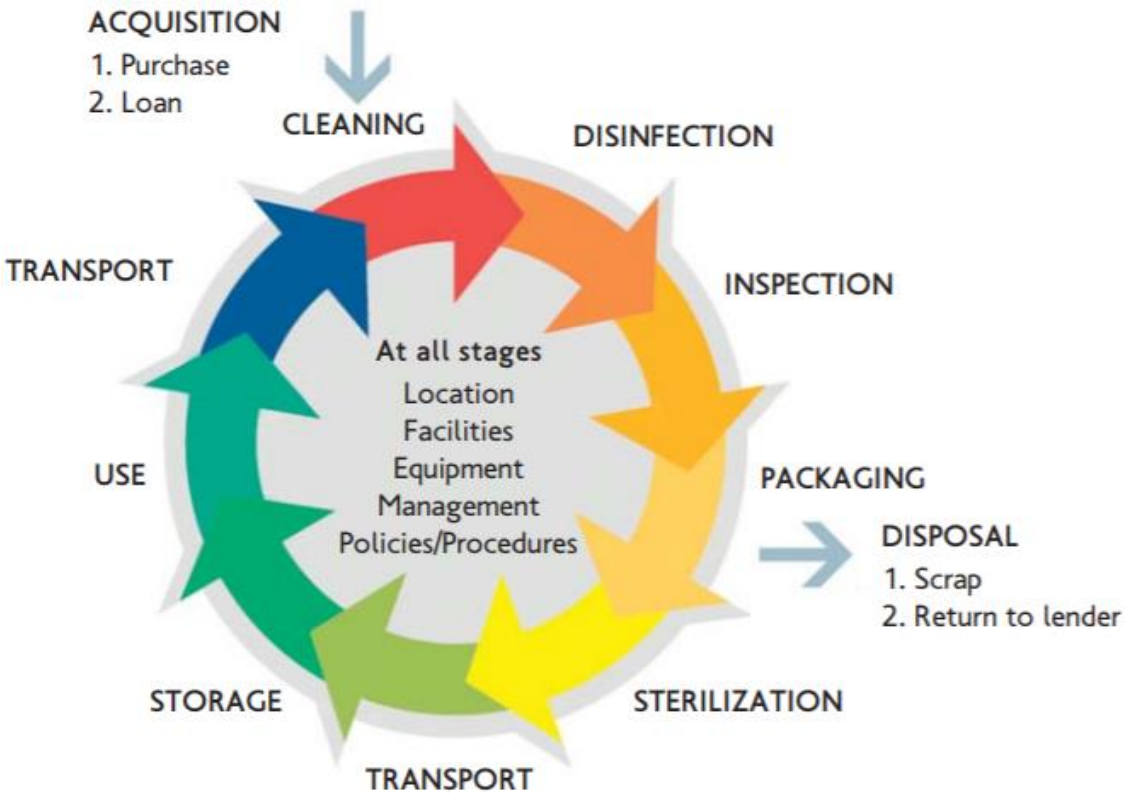

Figure 8: The logistics loop of the reusable equipment (WHO, 2016)

There can be multiple levels of storage of reusable equipment in the sterile logistics loop. The hospitals often have centralized storages in connection to the CSPD, decentralized storages close to the point-of-use in the departments. The equipment is also often temporary stored in the OR before and after utilization (McDonnell & Sheard, 2012; van de Klundert et al., 2008).

(van de Klundert et al., 2008) explains the flow of reusable goods used in surgery, with the decentralized sterile storage in the department as starting point; Before an operation, the necessary equipment trays are drawn from the storage, or straight from processing, and moved to the OR. It is important to control that all the required equipment is in place before starting the procedure. In the next step the equipment is utilized in surgery. Post-procedure it is

important to handle and sort the equipment correctly so that they are not damaged, lost or thrown away by accident (McDonnell & Sheard, 2012). Whether used or not, all equipment is considered contaminated after moving through the OR. It is therefore transported to the goods receipt of the sterile processing department for processing (van de Klundert et al., 2008). The equipment collection and dispatching of the return goods is often handled by nursing or logistics staff, and received by the sterile processing staff at the CSPD (Chobin & Swanson, 2012). The processes inside the CSPD are explained in chapter 3.2.5. After passing through the CSPD the equipment is sterilized and kept in central or decentral storages until next utilization, and that completes the closed loop. (van de Klundert et al., 2008) explains how the cycle from usage an until replenishment often takes more than half a day, even with the CSPD close to the OR.

Through their logistics loops the trays of equipment are usually distributed by carts, like the once illustrated in Figure 9.

Figure 9: Distribution carts (Getinge, 2019)

In order to shed hospital personnel from logistics tasks, there has been a shift from manual handling of the material distribution, towards automating some of the tasks. Some of the solutions seen is automated transportation systems such as Automated guided vehicles (AGVs), pneumatic tube systems, robotic platforms and sophisticated conveyors (Bacik et al., 2017). Whenever the reusable equipment is transported outside of sterile zones, it should be contained in either a closed or covered cart, both when sterile and when contaminated (Chobin & Swanson, 2012).

3.2.5 The Central Sterile Processing Department

The central Sterile processing department (Swenson, 2013a), also called the Central sterile processing (CSP)(Kobus, 2008), the sterile processing department (SPD) (Chobin & Swanson, 2012; Kobus, 2008), the Central sterile supply (CSS)(Kobus, 2008) or the Central sterilization service department (CSSD) (van de Klundert et al., 2008), is an essential supporting service department in the hospitals (Kobus, 2008; Ma, Yang, Reeves, & Yu, 2012). The CSPD provides the medical practitioners with the required trays of reusable instruments, in the required condition, at a rate that supports the patient care and operation schedule of the hospital (Lin et al., 2008; Ma et al., 2012). Another, but similar, customer service goal of the CSPD is provided by (Johnson, 2005): " 100% clean and sterile instruments, 100% complete instrument trays, delivered to the O.R 100% on time."

(Kobus, 2008) and (van de Klundert et al., 2008) explains how the Central Sterile Processing Department, which primarily supports the surgical suite, should be placed in a central to the surgery department(s) in the hospital. It is therefore often located close to, below or above it the suite. The latter option would however benefit from direct access to two separate elevators for the transportation of clean and soiled equipment in between floors (van de Klundert et al., 2008). However,(van de Klundert et al., 2008) argue that using the valuable space next to the OR for care and cure rather than the secondary support process that sterile processing is, provides opportunity for improving the customer service.

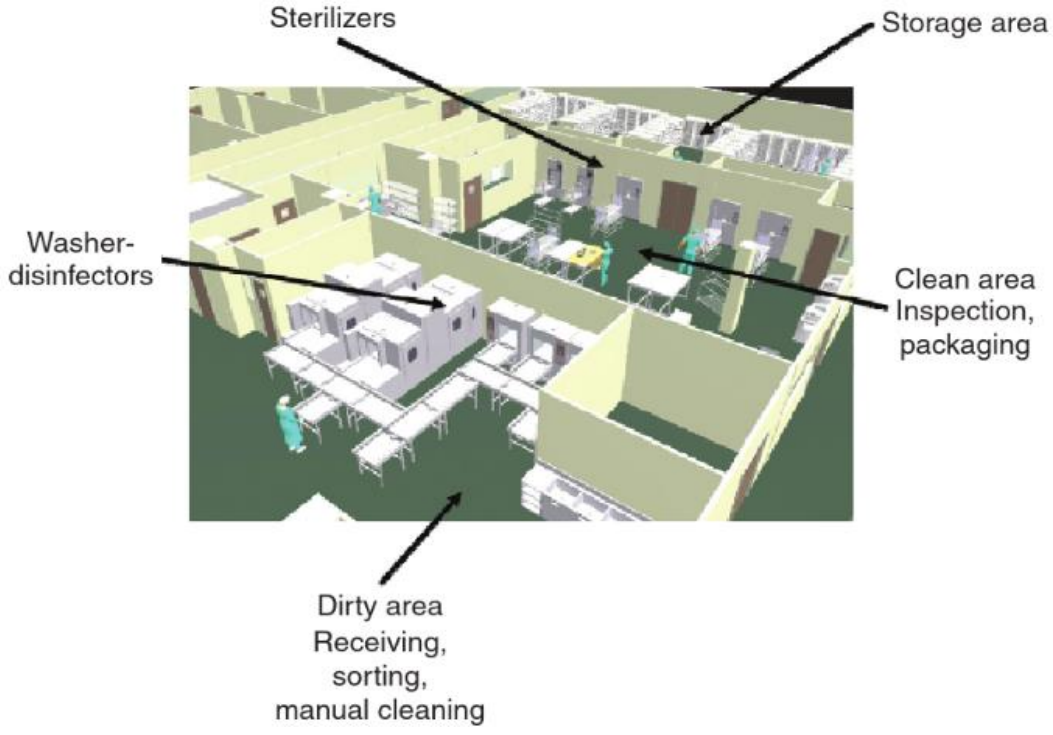

Figure 10: The CSPD (McDonnell & Sheard, 2012)

The CSPD is where the infection chain is broken. Soiled equipment arrives here after utilization and goes through the process of cleaning, disinfection, inspection and packing, sterilization, and lastly distribution and storage (Chobin & Swanson, 2012; Fineman & Kapadia, 1978; McDonnell & Sheard, 2012). The flow through the processing activities of the department is illustrated in Figure 11.

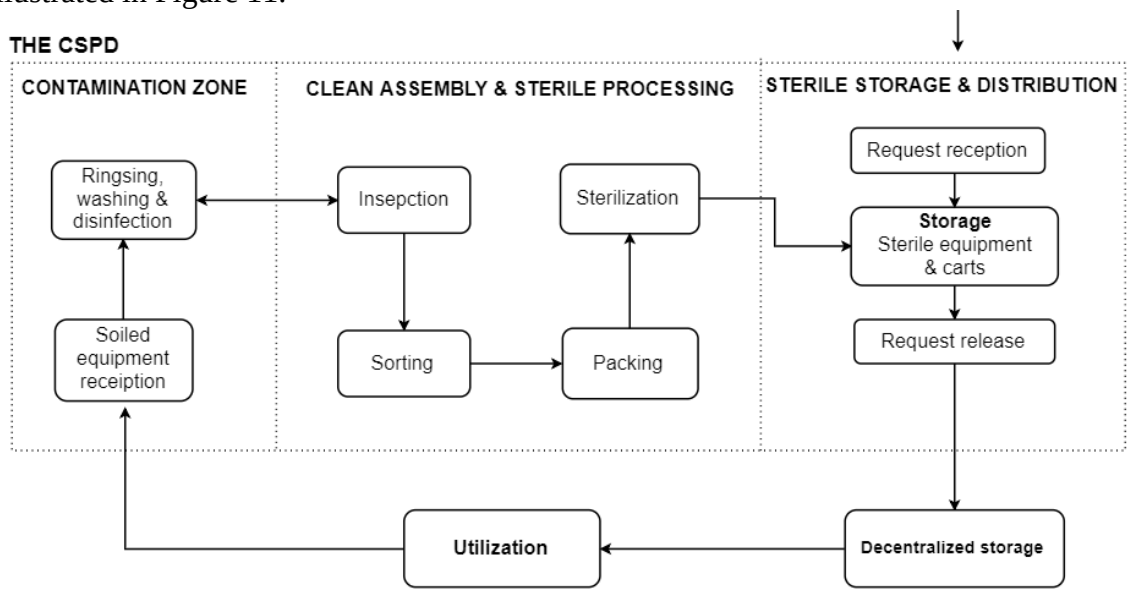

Figure 11: The processing activities in the CSPD

The department is under pressure to reprocess the surgical instruments accurately, efficiently and safely (Kobus, 2008). Careful attention is given to providing a work flow according to the requirement of keeping clean and sterile supplies separated from contamination (Kobus, 2008). In order to avoid cross contamination, the department is physically split into three separate areas; a sterile area, a clean area and a soiled area. As can be seen in Figure 13.

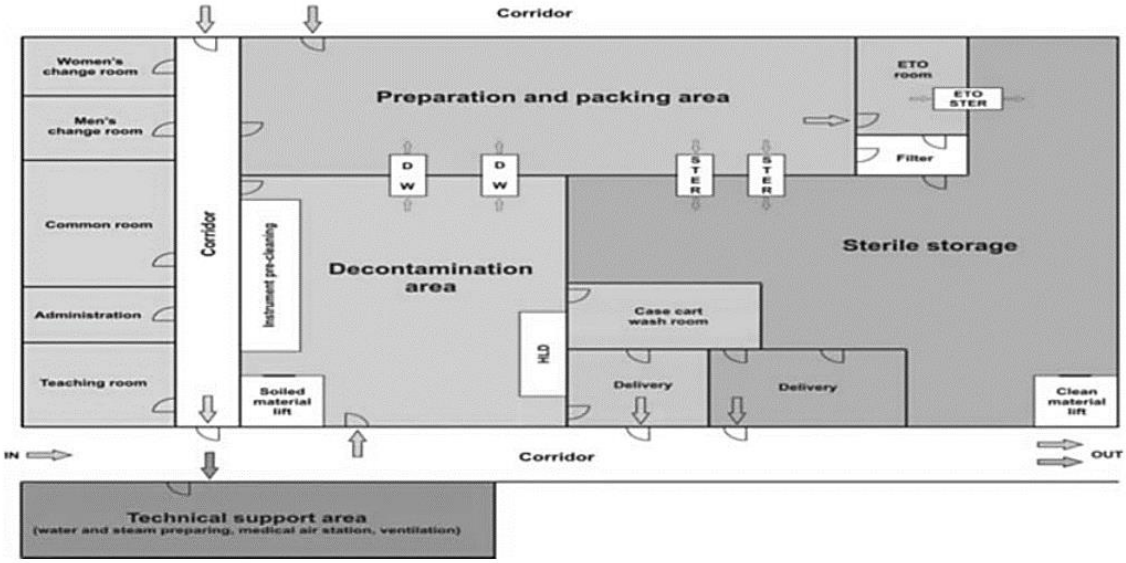

Figure 13: A typical layout of a CSPD (WHO, 2016)

The processes in the CSPD are highly dependent on manual labour and therefore characterised as labour-intensive (Di Mascolo & Gouin, 2013). The staff working in the CSPD require special certification and training. They are either stationed on the soiled, clean or sterile side. They cannot move from a zone with lower degree of cleanliness to one with higher, without taking the necessary hygiene measures and changing scrubs (McDonnell & Sheard, 2012).

The three zones of the Sterile Processing department are the following (Kobus, 2008):

1. Decontamination zone
2. Assembly & Sterile Processing
3. Sterile storage & distribution

In the following chapters the three zones will be described in more detail.

3.2.5.1 The Decontamination zone

The decontamination zone is where the soiled instruments arrive for initial gross cleaning and disinfection after being utilized in surgery or other procedures (Kobus, 2008). The returned instruments are often arrive in carts (WHO, 2016). For safety, all staff in the decontamination zone must be fully attired in personal protective equipment (PPE) to protect them from microbiological soil, chemical soil and sharp devices (McDonnell & Sheard, 2012). The carts used to transport the containers and equipment are considered non-critical items that must be routinely washed, preferably after each use, in order to avoid cross-contamination. The cleaning of carts is often performed in the decontamination zone, either manually or by cart-washing machines (McDonnell & Sheard, 2012).

The cleaning process is defined by (McDonnell & Sheard, 2012) as “the removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.” It may include removal of materials such as blood, human tissues, microorganisms and chemicals such as cement and gels that may be used in procedures. Some of the equipment need to be disassembled in order to expose all surfaces to the cleaning process. Cleaning is a prerequisite for all equipment arriving in the decontamination zone. For the devices characterized as non-critical according to Spaulding scheme, cleaning is the only required step of reprocessing (McDonnell & Sheard, 2012; Spaulding, 1968). Disinfection is defined as the “antimicrobial reduction of microorganisms from a surface to a level determined to be appropriate for its intended further handling or use”(McDonnell & Sheard, 2012).

Based on manufacture instructions and standard operating procedures the cleaning is performed by applying one or more cleaning methods such as; manual cleaning, spray-gun rinsing, chemical disinfection, ultrasonic machines or by disinfecting washing machines (Di Mascolo & Gouin, 2013; Kobus, 2008; Ma et al., 2012). The amount and type of washing devices and machines in the decontamination area depends on what types of services the CSPD supports(Chobin, 2001). However, most modern CSPD have automated washers that handles a large share of the equipment. The washers allows for larger handling capacity, standardization of the process as well as minimum handling of decontaminated equipment by the staff (McDonnell & Sheard, 2012). The washers can be tunnel washers, multi chamber washers, single chamber washers, cart or large chamber washers (McDonnell & Sheard, 2012). To avoid cross-contamination the washers are arranged so that point of entry is on the contaminated side, while the point of exit is on the clean side (Kobus, 2008).

The capacity of a washer is often referred to as the number of standard trays of devices it can hold. (Di Mascolo & Gouin, 2013; McDonnell & Sheard, 2012) describes how the washers process batches of instruments at the time and explain two different policies for loading the washers. The first policy tries to maximize the machine load by filling the washer up to a given filling threshold before washing is performed. The other applies a waiting time threshold, were washing is cyclically initiated after a given waiting period. The purpose of this policy is to minimize work in progress. The washers could also be filled either according to a FIFO principle, or by a first fit policy were the waiting items are sorted and placed in the washers according to size (Di Mascolo & Gouin, 2013).

The washing step has been identified as the bottle neck of the sterilization services by (Ozturk et al., 2014). They study a parallel batch scheduling problem at a sterile department, with the objective of minimizing the make span of the sterile processing. (Kobus, 2008) explains that a noticeable trend in the decontamination area is automated loading and unloading of instruments in and out of the washer systems. The purpose is to reduce staff workload, eliminate heavy lifts and improve the workflow.

3.2.5.2 The Assembly and sterile processing zone

After rinsing and washing, the items move to the clean Assembly and sterile processing zone. The items are cooled down before they are brought to a workstation. Here they are inspected to make sure that they are intact and functional, and that no contamination is left to compromise the security of further processing (Di Mascolo & Gouin, 2013). In the cases were items are found unsatisfactory cleaned, they are returned through a return window for re-washing (Kobus, 2008). The equipment that pass inspection are carefully assembled and regrouped into trays, according to detailed instructions (Kobus, 2008; van de Klundert et al., 2008). Further, the trays or single equipment are wrapped or packed in nonwoven textile wrapper, ridged container systems or in heat sealed plastic or paper pouches. The wrapping represents a barrier for unwanted microorganisms, while at the same time allowing for good penetration of the sterilizing agent (Di Mascolo & Gouin, 2013). The packed equipment and trays are relabelled with a new barcode which contains basic information about the equipment, such as item-ID, reprocessing date and expiration date, which tells when the equipment must be reprocessed again even if it have not been used (Ma et al., 2012). The trays are placed in racks and ready for the final sterilization. The sterilization is also carried out in batches, with a the batch size that depends on the sterilizers tray capacity. (Di Mascolo & Gouin, 2013)

Equipment commonly used for sterilization are high-pressure sterile processing systems (steam or electric), chemical sterilization systems or plasma sterilization. (Kobus, 2008) (van de Klundert et al., 2008) explains the majority of hospitals uses high-pressure steam sterilization by the use of autoclaves. The sterilization area is usually joined into the assembly area without any physical barrier between the areas. But in the same way as the washers, the equipment are loaded into the sterilizer on the clean side, but retrieved in the sterile zone (WHO, 2016).

An extensive literature stream exists on the topic of the different sterilization processes, with regards to their practises, quality control and the science behind the methods. An overview of the basic sterilization methods are described by (Hunter, 2013). All aspects of the decontamination process is explained in (McDonnell & Sheard, 2012)'s practical guide to decontamination in health care.

3.2.5.3 Sterile Storage & Distribution zone

This zone is responsible for storage, replenishment and dispatching of the sterile equipment and exchange carts (Kobus, 2008). This is also where the procedure specific carts are prepared, and the orders arrive by phone or requisition order filing. After sterilization, the instruments are placed in the sterile storage and distribution zone until issued, or directly transported to their respective departments (Kobus, 2008).

Both storage and transportation can compromise the sterility. Necessary measures and environmental control must be provided to maintain the sterility of the equipment until use in immediate or future patient procedures. Best practice for maintaining sterility of the equipment is to minimize handling, and to store and transport correctly (McDonnell & Sheard, 2012). The storage area must therefore be designed to facilitate for the specific hygiene and infection control requirements. It should be physically separated from other areas, shed from traffic and access should be limited to only the necessary staff (McDonnell & Sheard, 2012). Sterile items should be arranged so that handling is minimized and so that locating the different procedure trays is made easy. A tracking system can also be helpful in identifying and locating the different equipment (McDonnell & Sheard, 2012).

(Ahmadi et al., 2018) explains how the management of sterile instruments basically comes down to answering three questions: " (1) which instruments and in what quantity should be placed in each tray type, (2) which tray type should be used for a given surgeon and procedure, and (3) how many of each tray type should be stocked in inventory. Where the latter question depends on the frequency and scheduling of the different procedures.

Some literature exists on the topic of optimizing the inventory levels of sterile equipment. (Little & Coughlan, 2008) introduces a model for deciding on the optimal inventory policy within the hospital space constraints. While (Fineman & Kapadia, 1978) studies the appropriate level of stock, under the assumption that demand is constant. (van de Klundert et al., 2008) seeks to reduce the overall inventory management cost by optimizing the compositions of trays and implementing pull logistics for certain types of surgery trays. (McDonnell & Sheard, 2012) discusses how larger inventories will require larger storage area and higher cost but reduces the risk of running out of stock and emergency situations will be easier to deal with. When deciding the appropriate stock levels the reliability and lead-time of supply must be considered, against the uncertainty in demand. (Birk, 2007) and (McFaddin & Earnhardt, 1999) looks into tackling the problem of limited sterile storage space by implementing mobile storage solutions. While

(Williamson, 2011) looks into the challenge of not compromising the sterility of stored items until the point-of-use.

When it comes to distribution of the sterile equipment (McDonnell & Sheard, 2012) explains that movement of the equipment trays can be carried out by gentle hand holding, but for longer transportation cart systems should be considered. When appropriate dedicated lifts, one clean and one for soiled goods, can be used for direct transport of equipment between the dispatch area, point-of-use and to the goods reception in the decontaminated area. In the past, the sterile storage and distribution department was often responsible for the distribution of sterile single-use items also. However, having specially trained and certified staff manage this is unnecessary, so the management of them are often separated from the CSPD (Kobus, 2008).

3.2.5.4 Demand characteristics and replenishment policies

The demand for sterile equipment will depend on what surgeries and procedures, scheduled or unplanned, that are carried out in the hospital every day (van de Klundert et al., 2008). The workload of the CSPD is equal to the amount of soiled equipment that arrives. The soiled equipment arrives at different times during the day, often in bursts that coincide with the surgery completions, which tends to complicate the staff scheduling (Lin et al., 2008). The volume of equipment arriving will differ based on the surgery characteristics and equipment tray requirements (Ozturk et al., 2014). However the arrival patterns often result in significant accumulation of equipment throughout the CSPD (Lin et al., 2008).

(van de Klundert et al., 2008) explains the processes and equipment requirements in the operating rooms as unpredictable by nature. This is due to several characteristics, such as the fact that many of the patients arrive unexpectedly as emergency patient and may need immediate surgery. Even if the surgery is planned it frequently happens that surgeries evolves in an unexpected manners and additional sterile equipment will be needed. It can also happen that the trays of sterile equipment are incomplete or that their sterility is compromised before surgery.

How the CSPD should operate to best meet their demand depends on the degree of predictability in demand. If most surgeries are unplanned and hard to predict, the best way to replenish the used equipment may be to process and return it as quickly as possible to sterile storage. However, if large fractions of the surgeries are planned and executed according to plan, it can

be more efficient to base the replenishment plan on the known information (van de Klundert et al., 2008). But basically, the only way to make sure that the hospitals are able to deal with unplanned use of equipment trays is however to keep safety stock of them. (van de Klundert et al., 2008) explains how many hospitals processes all the equipment drawn from storage and utilized in one day, so that at the end of the day they are again to find in the sterile storages up in the hospital department again.

3.2.5.5 People, jobs and organization

Skilled and dedicated staff are often considered the most valuable resource of every reprocessing area (McDonnell & Sheard, 2012). The processes of the CSPD are knowledge- and labour-intensive, at times very busy and relies heavily on its employees. And according to (Swenson, 2013b) a majority of sterile processing departments today provide a 24-hour coverage. (Basu, Bhattacharya, Mahajan, Ramanan, & Chandy, 2014) explains how investing in recruitment and continuous training of technically qualified human resources is just as important as the physical resources and infrastructure of the sterile department. The employees of the CSPD must be able to operate the system efficiently, know the importance of infection control and understand their role in the process.

The employees often range from multitasking medical staff with sterile processing as a part of their job description, to full-time dedicated reprocessing teams. Today decontamination has become a specialized and internationally recognized profession (McDonnell & Sheard, 2012). The workforce required will depend on the size and characteristics of the sterile department, the skill and flexibility of the staff, as well as the number of surgical procedures carried out by the hospital (McDonnell & Sheard, 2012; Swenson, 2013b).

(WHO, 2016) lists factors that influence the staff requirements per shift, such as:

- **Peak times:** Most of the operations and procedures are executed within given timeframes that causes peak times of workload for the CSPD.
- **The number of available surgical trays and equipment**: If the volumes are insufficient to fulfil the requirements of the operations for a given period, the more frequent cycles of sterilization must be run, and the more staff is required both day and night.
- **Outsourcing vs In-house**: If the surgical trays needs to be transported longer distances to be processed in the CSPD, the workload and staff will depend on shipping frequency and volume.

When it comes to the organization of the CSPD staff, this vary from department to department. But no matter the size of the CSPD, there will always be a need for assigning clearly defined roles and responsibilities to the different employees. (McDonnell & Sheard, 2012) explains how a standard organization and division of labour in the sterile department consists in the following roles:

Department manager: Needs to be highly skilled and thoroughly understand the entire process. Responsible for managing staff, budgets and all functions of the reprocessing area.
Section manager: Highly qualified in the field of reprocessing services. In charge of the day-to-day management of staff and services, as well as training the staff an maintaining required standards.
Team leader/supervisor: Each processing zone should have a team leader that is in direct contact with the processing staff and responsible for running the particular area.
Technician/operator: Staff with different level of expertise, in charge of carrying out the actual reprocessing tasks. Often able to switch between the different tasks

Below management level the organization structure of the CSPD is based on grouping resources together according to their functional purpose or work-zone. It is however typical to have job rotation between the three zones and the different processing activities(McDonnell & Sheard, 2012).

Within the literature that exists about staffing at the CSPD, a large share is concerned with the relationship and collaboration between the staff of the CSPD and the staff of the operating room. (LeBouef Joseph, 2011) explains the relationship between the OR and the CSPD as a complex “love/hate relationship”. Both departments are dependent of the other for success, but despite this symbiotic dependence, the communication and cooperation across the departments is often strained. (Stewart, 2004) and (Seavey, 2010) are among the authors that studies measures for “tearing down the walls” between the SPD and the OR.

3.2.5.6 Processing technology & ICT

Essential operations of the sterile processing are performed by the use of processing technology in the shape of the washing and sterilizing machines. The quality of the processes is dependent on technology to continuously monitor the state of the machines, to ensure their functionality. There is also need for technology to monitor environmental factors such as the humidity and temperature in the CSPD. (Swenson, 2013b) And lastly, information and communication technology is an important tool in the CSPD. ICT comprises any technology that collects, manipulates, stores and shares information (Slack, 2013).

(McDonnell & Sheard, 2012) explains how the processes, materials, personnel and quality are important areas to manage in the sterile department. Information technology is an important tool in doing so. It can enable for monitoring, visualising, tracking and controlling of the processes' execution and communicate necessary information to the CSPDs' customers. (Swenson, 2013b) underlines how "Computerized management systems are needed to ensure that the department operates at optimum efficiency and does so effectively."

(Bailey, 2001) explains how a computer management system should be able to perform several operations. One of the most important functions is to educate, provide instructions and detailed information to assist the sterile processing technicians in performing activities like tray decontamination, assembly and packing. Other important functions are to collect and report activity and productivity data. It should keep track of routine maintenance, keep records of the executed processing activities and facilitate for accurate inventory management and good communication across departments involved. A good system should also be well incorporated into the workflow, so that the technicians don't have to stop their work unnecessarily in order to record the different events. The system should employ user friendly devices such as touch screen technology, bar-codes and handheld scanners (Bailey, 2001).

(van de Klundert et al., 2008) explains how most hospitals use information systems to keep track of the planned surgeries and procedures. It is however quite common that the activities at the CSPD is not integrated in these systems, but is executed and planned independently. (Swenson, 2013a) investigates how benchmarking can be a helpful tool in the process of designing and developing a central sterile supply department. By comparing seven facilities she concludes that some features, such as having a continuous improvement program, monitoring programs and integrating the use of computerized management systems are prerequisites in a modern CSPD.

Management of the processes and flow of goods inside and outside of the CSPD can be enhanced using tracking and tracing systems. The aim of the tracking systems is to ensure efficient and accurate flow of equipment between the CSPD and the point-of-care. Ideally the systems should be able to track the reusable equipment through the entire sterilization loop. In this way interesting utilization patterns can be identified and evidence that the equipment has been through the required processes to be ready for patient-use is provided. It has shown effects such as reduced instrument loss, optimization of utilization and inventory management, maximization of employee productivity reducing delays in delivery to the OR and thereby also downtime in regard to the core activities of the hospital (Ahmadi et al., 2018; McDonnell & Sheard, 2012). Additionally, (Bailey, 2001) argue that tracking the equipment through the entire loop establishes a more accountable system with fewer misplaced and damaged instruments. Having accurate numbers on tray usage also creates a good basis for making valid decisions regarding instrument mix, inventory volumes and staff requirements.

(Ahmadi et al., 2018) explains how track and trace systems often use information technology systems in combination with data capture technologies such as RFID and bar code, for collecting real time data and sharing this information. Several practitioners and academics such as (Goh, Tan, & Leong, 2016; Ma et al., 2012; Rosales, Magazine, & Rao, 2014) highlights the fact that such systems is a prerequisite for improved management at the CSPD. At the same time, the use of barcode and RFID have its limitations. Barcoding requires personnel time and is prone to human error. RFID tags and trackers provides an alternative to the labour-intensive barcoding, however these are advanced technologies that require high investments in technology infrastructure. It is however predicted that these technologies will become more cost-effective in the future (Ahmadi et al., 2018; Moons et al., 2019) .

3.3 Designing the CSPD

The design and configuration of the CSPD will vary due to factors such as the size and demography of the population the it serves, the amount of operations it is to support and the distance between the CSPD and the departments it serves (WHO, 2016). According to (McDonnell & Sheard, 2012) a correctly designed CSPD is the first step towards ensuring patient safety. The design must allow for safe reprocessing of the medical devices, provide a unidirectional workflow form dirty to clean, be able to handle the required workloads and facilitate for an ergonomic and efficient working environment for its staff, with the financial resources that is at hand. It is a challenge to choose a design that fulfil all the requirements and at the same time focuses on the functionality and integrity of the department (McDonnell & Sheard, 2012; WHO, 2016).

(Chobin, 2001) investigates the process of planning, designing and monitoring the construction of a sterile processing department. Two construction scenarios are discussed; the construction of an entirely new SPD or renovation of an existing SPD. Both scenarios provide the opportunity for designing a state-of-the art processing department that facilitates services with high quality and optimal efficiency. (Chobin, 2001) underlines that in order to accomplish this, planning is key. The result should be designed and constructed in a way that improves the physical layout, workflow, traffic flow and staff member productivity.

The space and capacity requirement of the CSPD in total will depend on the demand placed upon it. This is closely related to factors such as the size of the institution/hospital, the number of beds relying on the departments' services, average surgery numbers and types, the operating hours of the SPD and the number of employees per shift (WHO, 2016).

(WHO, 2016) and (Kobus, 2008) also explains how the three zones of the CSPD must be carefully developed according to their purpose, functions and space requirements.. In Table 5 a list has been provided with the main take-outs from (WHO, 2016), (Chobin, 2001) and (Kobus, 2008) when it comes to space and layout considerations and some possible equipment requirements, for each of the individual zones.

Table 5: Take-outs on design considerations for the three zones of the CSPD

Decontamination zone:
Space & layout: • There should be sufficient space for the required processing devices and to operate them. • Manual cleaning may require more area than automated. • Include apace to incorporate equipment for flexible endoscopy cleaning if this is offered by the CSPD. • Distribution method for the processed equipment must be considered. Space requirements for soiled elevator or cart systems with associated storage, cleaning and parking of the carts must be calculated. • There should be enough space to hold patient care equipment and case carts that are awaiting processing. • There should be sufficient counterspace or worktables for unloading and sorting of the used equipment. • There must be room for disinfection of the carts, manually or by cart washers. • Space must be provided for all cleaning supplies and equipment. • The area must be physically separated from any clean or sterile areas. • There should be a separate entrance from the corridor. • There should be a pass-through window for passing manually cleaned devices **Equipment:** • The required decontamination machines/equipment. • Table or surfaces for registering and sorting the devices • Sinks purposefully designed for manual cleaning and disinfection of medical devices. • Cold water jet guns • Shelves for storage of chemicals and cleaning items • Endoscopy reprocessing equipment if offered as a service by the CSPD. • Disposal of liquid and solid waste • Hand hygiene facilities.
• **Assembly and sterile processing zone:**
Space & layout: • Plan to have enough space for the sterilizer carts and carriages to be parked in front of the sterilizers. • There should be an area for logging and storing sterilization records. • Decide on the required number of workstations and countertops, and if they should be movable or built in. • There should be storage for packing and other necessary supplies. • Include an area for biological indicator testing and incubation. **Equipment:** • Worktables for sorting, assembly, packing, wrapping & record keeping. • Shelves & Racks • Workstation for heat sealing • Chairs • Magnifying lens with light • Closed cabinets for storing clean instruments, medical devices and packing supplies. • Steam sterilizers • Low temperature sterilisers • Chemical sterilization
• **Sterile storage and distribution zone:**
Space & layout: • It needs to be a segregated area with traffic control. • If equipment is stored in containers, these take up more space than wraps, which must be accounted for. • There needs to be space for the processed trays to cool off after sterilization. • There must be sufficient storage space for storing the quantities of equipment needed, space requirements will depend on storage solutions. • There should be enough space for storing of carts waiting to be filled. • There should be a dedicated clean transport system to the OR.

- Some CSPD have a dedicated clean/sterile lift for delivering sterile equipment to the point-of-use.
- Should not have windows.

Equipment:

- Shelves for storage
- Open shelving that allows good air circulation
- Desk for record-keeping prior to dispatch of goods
- Phone & computer desk
- Dispatch and transportation system for sterile packs

In addition to the three processing zones, other functions to be incorporated into the design are entrances, exits, corridors, staff changing rooms, offices and areas.(WHO, 2016). Access to the CSPD should be restricted to authorized personnel only. When entering it should be through airlocked changing rooms and specific dress codes and hygiene practices must be followed (Basu et al., 2014). There must also be space from common central supply of essentials such as high quality water, medical quality air and pre-generated steam supply to the sterilizers

Layout & Workflow

(McDonnell & Sheard, 2012) explains how serious consideration should be given to the designing appropriate layout and workflow in sterile processing facilities. They emphasise that it is too often the case that the departments areas are found to be inadequate. The layout of the CSPD should be physically divided into separate areas, with a clear unidirectional workflow of both equipment and staff, from dirty to clean (Basu et al., 2014; WHO, 2016). As illustrated by (McDonnell & Sheard, 2012) in Figure 14. In order to ensure the reliability of the process, it is important to implement quality control in to the workflow. (Basu et al., 2014) After quality is ensured, the workflow must also be maintained to maximize the productivity (Blake, 1990). Maintaining a good workflow implies the need for proper functioning and coordination between the distinct zones (McDonnell & Sheard, 2012).

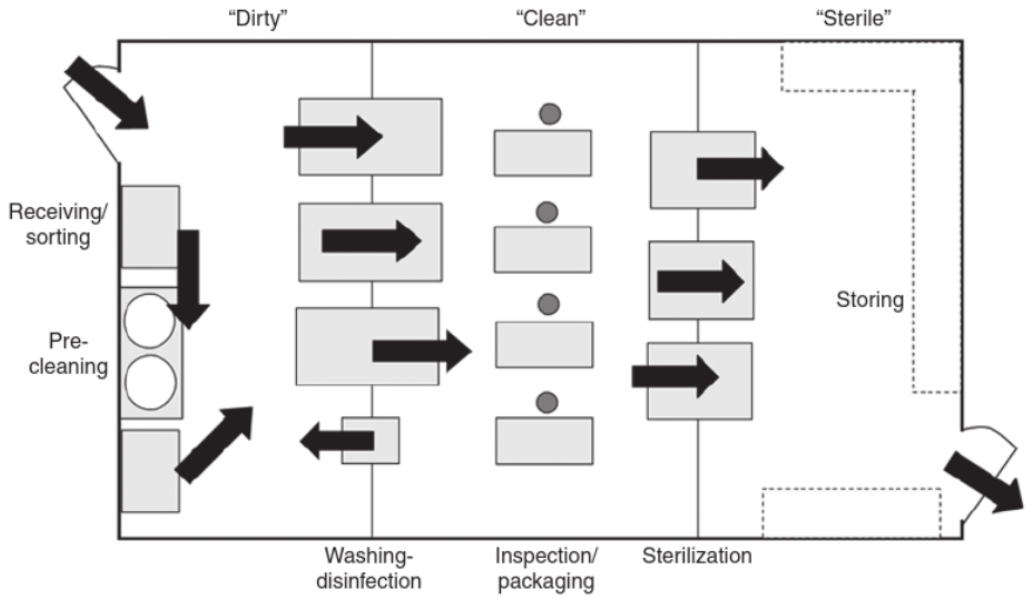

Figure 14: Layout and unidirectional flow in the CSPD. (McDonnell & Sheard, 2012)

(Johnson, 2005) studies optimizing of the sterile processing workflow. He explains how an effective sterile processing workflow should incorporate the specific needs of the reprocessing operations and related systems, automate wherever it is possible, while eliminating the redundancy and process variability. With the goal of accomplishing more with less, strengthening the quality, heightening the speed and reducing the occurrence of error. Which ultimately results in providing the end-customers with a better-quality service, at the proper time and cost.

Characteristics of effective CSPD workflow as provided by (Johnson, 2005):

1. They streamline value adding activities and eliminate waste.
2. They are consistent and facilitate for simple, repeatable, reliable and efficient processing tasks.
3. Compatible with hospital practise and easily integrated with associated systems.
4. Should have bottleneck flow that is on par with demand, balancing the flow, not the capacity.

Among the concepts that has received attention in the mission of optimizing workflow is the process improvement method known as lean. The focus of lean is to concentrate the value-adding activities of the process and eliminate waste, variability and non-value-adding activities. Increased attention have been given to applying lean to the entire sterile supply loop and improving the process efficiency throughout the entire operation.(Johnson, 2005)

Environmental & ergonomic requirements

Construction of a CSPD presents some unique challenges in terms of the many environmental requirements that must be fulfilled in order to provide the right conditions for high quality sterile processing and storage (Chobin, 2001). Some of the main environmental considerations to be taken is provided in Table 6.

Table 6: Environmental & Ergonomic requirements of the CSPD

Surfaces	Surfaces on workstations, walls, floors and ceilings should be smooth and impervious to minimize the shedding and accumulation of particles. Walls are often plastic painted and the floors epoxy coated (Basu et al., 2014). Avoid anything that hard to keep clean, such as sliding doors and or interior with little nooks or crannies (Cole, Hall, Hoar, & Puri, 1998). Ergonomic considerations to be taken is that the floors must anti-slip and have an appropriate hardness so that it is not tiring to stand and walk on. Stationary workstations should have shock-absorbing mats that complies with the hygiene requirements (Hall-Andersen & Broberg, 2014) .
Drains and sinks	Drains and sinks, should be avoided when possible. If installed, they must have a easily cleaned trap and an air break to prevent backflow. In the sterile and clean area drains and sinks should be excluded (Cole et al., 1998).
Water quality	The quality of water is integral to the cleaning process, as well as the steam produced for the sterilizers. In order to avoid corrosion, mineral-free water should be used on all types of surgical instruments (Basu et al., 2014).
Temperature	Temperatures should be adjusted to provide comfortable working environment. It is important that heat generated by processing equipment dissipates quickly so that the temperature doesn't increase above recommended levels (WHO, 2016): Decontamination area: 18-20℃, Clean areas: 18-23℃, Sterile storage: 15-25℃
Humidity	The relative humidity is recommended to be at 40-50%, if it is to rise above this condense may form inside the sterile containers and the integrity of the sterile barrier is threatened (WHO, 2016).

Air quality	Air supplied to the SSD should be of medical quality. This means that the air will be free of bacteria, virus, chemicals and unwanted particles (WHO, 2016).
Air exchange rate	The general recommendation by (WHO, 2016) is to have no less than 20 air changes per hour.
Air flow	Air flow should go from clean to dirty area, not opposite, this is regulated by relative air pressure relationships and should be included in the design (Basu et al., 2014; Kobus, 2008).
Noise	For the comfort of the staff the department should be designed to minimize sound levels, this require particular attention to be given to the installation of the equipment, building finishes and machine maintenance (WHO, 2016).
Light	Stationary workstations must have daylight access. However, the workstations should be organized so that the gaze direction of the employees is parallel with the windows, to prevent glare from the sun (Hall-Andersen & Broberg, 2014).

(Hall-Andersen & Broberg, 2014) investigates how ergonomics considerations can be integrated in the process of planning the sterile processing department. In addition to the above-mentioned factors some more considerations are emphasised. When it comes to space requirements, it is important with enough space in the workplace to establish safe and sound work processes. In example, a lack of space in the assembly and packing area might lead to undesirable twists to move around with the equipment and should be avoided.

Simulation for design

(Di Mascolo & Gouin, 2013) emphasise how the decisions-makers in the sterilization services usually are more concerned and aware of aspects such as quality, safety and traceability, rather than organizational factors. They explain how CSPD services are highly strategical and organizational changes are rarely employed without knowing in advance that it will result in improvements. That's why (Di Mascolo & Gouin, 2013) employs simulation to investigate possible process improvements obtained by changing some organization aspects of CSPD, such as operation times and loading policies of the washers and autoclaves. (Lin et al., 2008) investigate how simulation can facilitate the design of a central sterilization department. A simulation model is built to analyse department configuration, equipment capacity, staff

schedules and cart-wash requirements. The results are analysed based on performance measures such as tray turnaround time, the rate of delayed surgeries and levels of WIP.

4. Empirical background

This chapter presents the empirical background of the thesis in the form of two case studies. Each case chapter starts with a case description and a detailed explanation of the current process design at the sterile departments. Before interesting insight from the cases are presented. The first case hospital is Stavanger University Hospital. They are currently operating with sterile functions who are highly fragmented and split across the hospital department. The hospital is however in the process of planning and designing a new Central Sterile processing Department as a part of their project "SUS2023". The case provides interesting insight into the process of planning and designing the processes of a CSPD. The second case hospital is St. Olav University Hospital. The hospital already has a centralized sterile processing department that serves the entire hospital. The case provides insight into the operations of the CSPD, and how its functionality is linked to the process design.

4.1 Case description - Stavanger University Hospital

Stavanger university Hospital is one out of six public University Hospitals in Norway. The initial hospital was built in 1927 with expansions in area until 1982. It is located in Våland and serves a population of 369 000 habitants south in Rogaland. The hospital has 587 patient beds for general treatment. In 2018 the hospital treated 33 160 inpatients, 15 714 outpatients and 107 813 polyclinical patients. (Helsedirektoratet, 2018) The hospital consists in several clinics and medical centres that provides both acute and planned medical treatments.

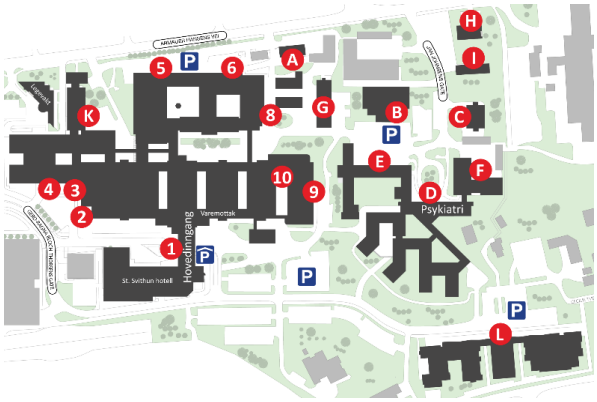

Figure 16: Overview Stavanger University Hospital at Våland

Figure 15: Stavanger University Hospital at Våland

In 2016 the project to build a new University hospital at Ullandhaug in Stavanger was initiated by Helse Stavanger HF. The project named SUS2023 will be built in several steps. The first step will be ready for use in 2023, it consists in the construction of four main buildings connected by bridge, as illustrated by the architect drawing in Figure 17. The plan is to move all somatic inpatient care, a ward of 640 beds, emergency functions, necessary radiology and

laboratory functions, as well as associated support and service functions to the new buildings by 2023. While the main portion of all outpatient and polyclinical activity and psychiatry is to remain at the hospital in Våland. The new hospital will be located approximately 3 km away from the current hospital at Våland. Goods and services will for some functions have to be delivered from one hospital to the other.

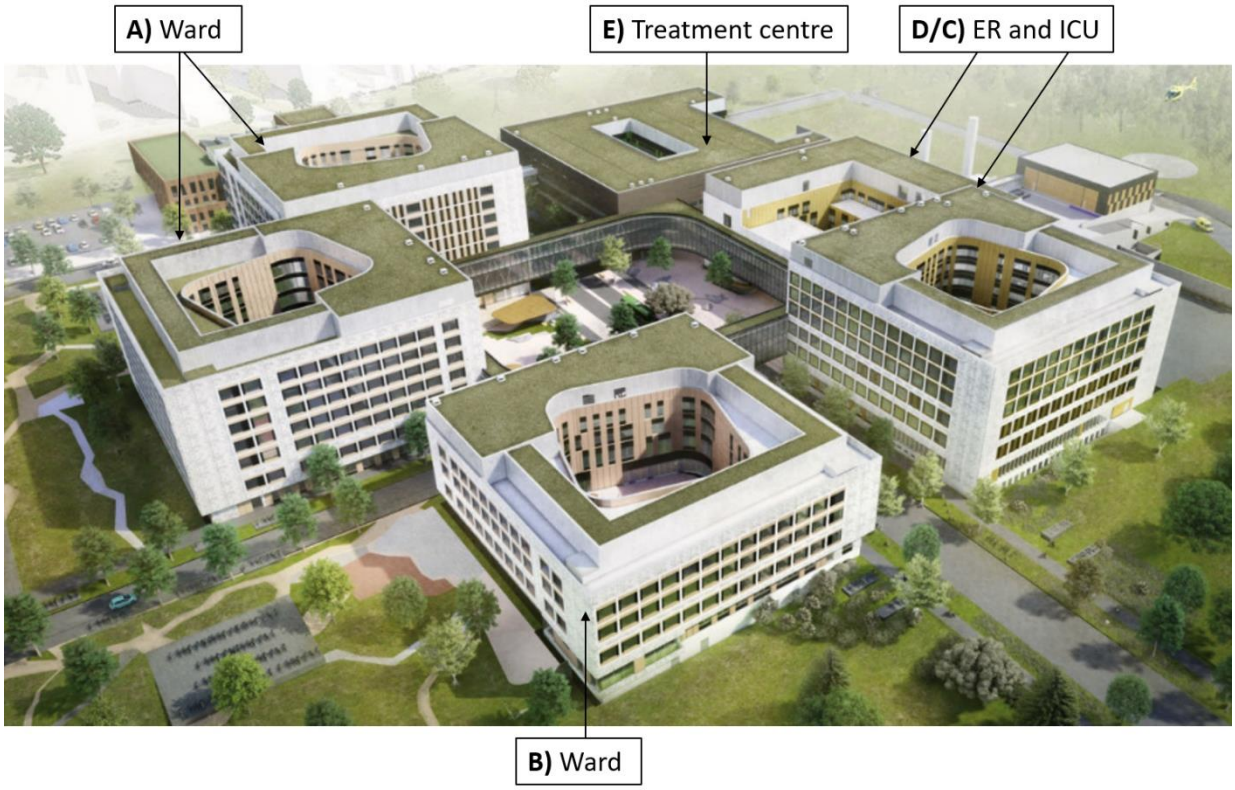

Figure 17: Architect drawing of the new Hospital at Ullandhaug

4.1.1 The SPD - AS IS

The sterile processing department (SPD) as it is today was opened in 1983 in the "south-building" of the Hospital at Våland. It is located on the technical floor below the surgical department.

Table 7: General information on the SPD at Stavanger University Hospital.

Operating hours:
Weekdays: 7.30 AM – 10.30 PM
Saturday: 8 AM – 3.30 PM
Sunday: 9.30 AM – 5 PM
Shifts: 3-shift system at weekdays.
Morning shift: 7-30 AM – 3 PM
Day shift: 12 AM – 8 PM
Evening shift: 3 PM – 10.30 PM
Employees:
Full-time employees: 30
Substitute employees: 3
Processing Lead times
Regular: 24 hours
Priority: As soon as possible

Today, the sterile functions in the hospital are not entirely centralized. The SPD is in charge of sorting, assembly, packing and sterilizing, while the decontamination processes are handled locally at several locations throughout the hospital. There are also local satellites for sterilization by smaller autoclaves in some departments. This is a necessary precaution since the SPD does not operate 24h a day. The department have 30 dedicated workers, that rotates between the different tasks in the SPD. Their operating hours can be seen in Table 7.

The workloads are highest between 11 AM and until 7.30 PM in the evening, mainly due to the operation scheduling. The departments must expect a lead time of 24 h from the equipment is delivered at the SPD and until it is returned in sterile state to the department again. The day before a surgery or procedure, the department staff check the storage rooms to make sure that the required equipment is available for use the next day. If this is not the case, they must place their orders by mail or phone to the SPD by 2 PM the day before.

The surgical department is responsible for the largest share of reusable equipment utilization. They have their own "decontamination zone" on the same floor as the ORs. After surgery the soiled goods is brought directly to this decontamination area. The decontamination room consists in a sink for manual wash, an ultrasonic washer and four tabletop washing machines integrated through the wall. On the other side the trays of equipment are cooled and sorted after best ability into the trays and placed in carts for further transportation. The room is small and at times chaotic, carts need to be stored outside in the hallways. There is no system or machine for washing the carts. From the surgical department there is a dedicated elevator system that transports the carts with clean goods down to the sterile processing department. On the technical floor, the carts are retrieved from the elevator by the SPD staff.

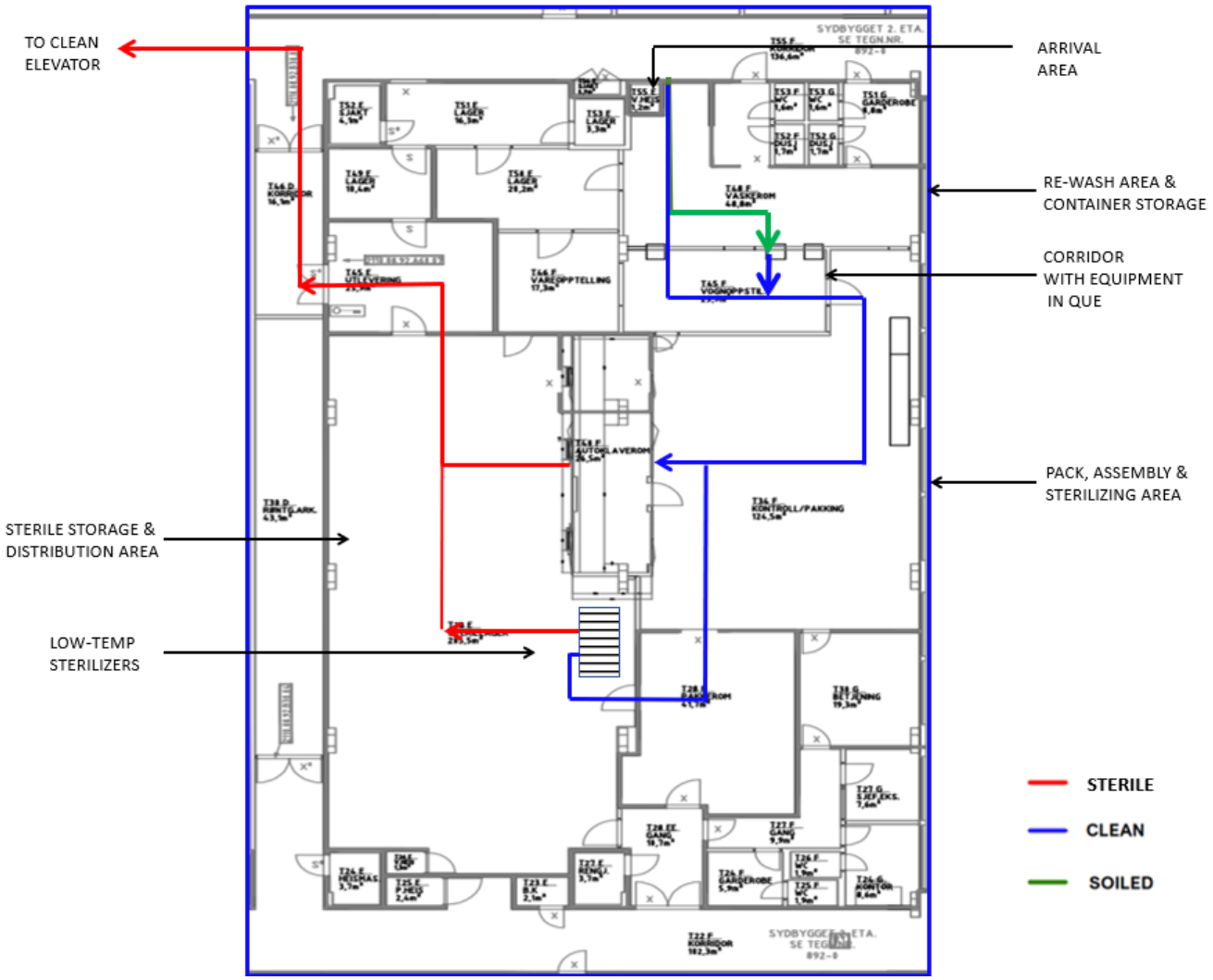

Figure 18: The layout & workflows of the SPD in Stavanger

The layout of the SPD can be seen in Figure 18. The SPD has a small washing area with two table-top washing machines and manual wash, mainly used in cases where arrived equipment is not found satisfactory clean upon inspection. Since there are little space for sorting the equipment up in the decontaminated zone of the surgical department, the equipment is further sorted here and placed in queue for further processing. Each tray is provided with a unique barcode with information on their intended content.

Figure 19: Trays of reusable equipment

The barcodes are color-coded, most sets have a regular white barcode. But some sets have red barcodes, this means that the tray is to be prioritized in processing. Red barcodes are often applied to sets with high frequency of use, which must be returned to the departments as fast as possible. The white barcode of a tray can be seen to the left in Figure 19

In the clean assembly and sterile processing zone, the equipment is inspected, controlled, assembled, oiled, and sorted into the correct tray configuration at the workstations. There is no fixed arrangement on what equipment is handled by which workstation. All trays and containers can be processed at all workstations.

Figure 20: Clean Assembly and sterile processing zone (StavangerHF, 2016)

The trays with equipment that is not concealed in a container is packed in two layers of non-woven fabric. Some single equipment and simple equipment sets are not stored in containers or trays, but rather packed in specialised bags, concealed by heating.

Figure 21: Packing of clean trays and single equipment (StavangerHF, 2016)

The equipment, whether sealed by paper wraps, bags or containers, are now ready for sterilization. The department have 3 autoclaves for steam-sterilizing built into the wall between

the clean and sterile zone. The sterilization takes 1 h 30 min and each autoclave machine can handle 20 trays at the time. There are also two smaller low-temperature plasma sterilizers, which are placed in the sterile storage and distribution zone.

After sterilization the trays are cooled down in the sterile storage and distribution zone. Most of the goods are held here temporarily before being directly sent up to the surgical department again by a specially dedicated clean elevator. The equipment that belong to the other departments is retrieved by the personnel of the department it belongs to. Some equipment trays that are infrequently used for specialized surgical procedures is stored down in the sterile storage. This is mainly equipment used by the orthopaedical department in planned surgery.

Figure 22: Unloading of Autoclaves, Sterile Storage and Clean Elevator (StavangerHF, 2016)

Tracking & computer management

Using barcodes, handheld scanners and a specialized ICT system called T-Doc, the equipment is tracked through the sterilization loop. The trays of equipment are scanned upon arrival in the SPD, when in packing, before and after sterilization, when sent to storage in the departments, when retrieved from storage and utilized in the surgical department and finally when delivered to decontamination.

Figure 23: Scanning barcodes for tracking in T-DOC (StavangerHF, 2016)

The storage position of the different trays and equipment is registered on the barcode, but the position is not provided in more detail than which storage room or which storage cabinet. The exact position of the equipment in storage is up to the

recollection and experience of the staff in the surgical department. This can sometimes lead to misplacement. Also, the system for when equipment is in utilization is not that precise. When retrieved for surgery the equipment barcodes are not scanned first thing. If the surgery lasts 3 hours, it often occurs that the operation nurse brings all barcodes for scanning after or during the surgery. The T-doc system is mainly used for this tracking, documentation and to provide instructions to the operators on tray configuration, assembly and packing routines. It is not integrated with the operation schedules, department orders or staff management.

Environmental concerns

The sterile processing department is characterized by the fact that it was designed to maintain the sterility requirements that was present in the 80s. These requirements have however changed a lot the last decades, and the environmental requirements are much stricter and more precisely defined today. In example, the ventilation does not regulate air pressure of the different rooms to provide an airflow from clean towards dirty. Temperature and humidity are not as easily regulated as in modern SPD. There is also a slight breach of the environmental requirements in the decentralized sterile storages, which has windows. The windows make the temperature harder to regulate and this may compromise the expiry date of the sterility of the stored equipment. The carts that move outside of the green sterile zone of the surgery department, and the dedicated clean and soiled elevators to the SPD, should be washed between each use. This is not provided in the sterile loop as it is today.

4.1.2 The CSPD - TO BE

The sterile functions of the hospital are among the supporting functions that will be relocated to the new Hospital at Ullandhaug. The aim is to centralize all steps of the sterilization process in a Centralized Sterile Processing Department. The CSPD will serve both the hospital at Ullandhaug and Våland with sterile medical goods. Both the reprocessing of the reusable goods and the sterile single-use items will be provided by the CSPD. The idea is that the CSPD can pack and deliver procedure specific carts to the OR, containing all equipment necessary, both reusable and single use items.

The CSPD will be located on the basement floor in the E-building directly beneath the new centralized surgery department located at the third floor. The CSPD and the surgery department will be directly connected by dedicated clean and soiled elevators. Deliverance and return to and from the other departments will be carried out by closed carts through the basement floor, using elevators and corridors to reach their final destination. The goods transported to Våland will be handled in closed carts and containers, placed at the good reception in the C-building and transported to truck, and returned in the same manner.

The working hours will be expanded to a full 24 hours a day service. There will be a specialized IT system to ensure the tracking and documentation of the processing of the reusable equipment. Most likely T-Doc. As it is today, the physical frame of the hospital as an entirety is set. Meaning that the area dedicated to the CSPD and placement of building pillars are already in place, based on the global design of the building. The internal design and layout of the CSPD is however a work-in-progress. The preliminary design explained in the following subchapter is most likely not the final design. When it comes to deciding on the inventory and processing equipment of the CSPD, this must be done in collaboration with the supplier of choice.

Preliminary design explained The preliminary design as of today is illustrated in “3D view” in Figure 24 and in “2D view” in Figure 25. Both illustrations are provided by the project architect Anne Underhaug. Figure 26 also includes illustrations of the flow of personnel and soiled and clean equipment, numeration is used for further in explanations

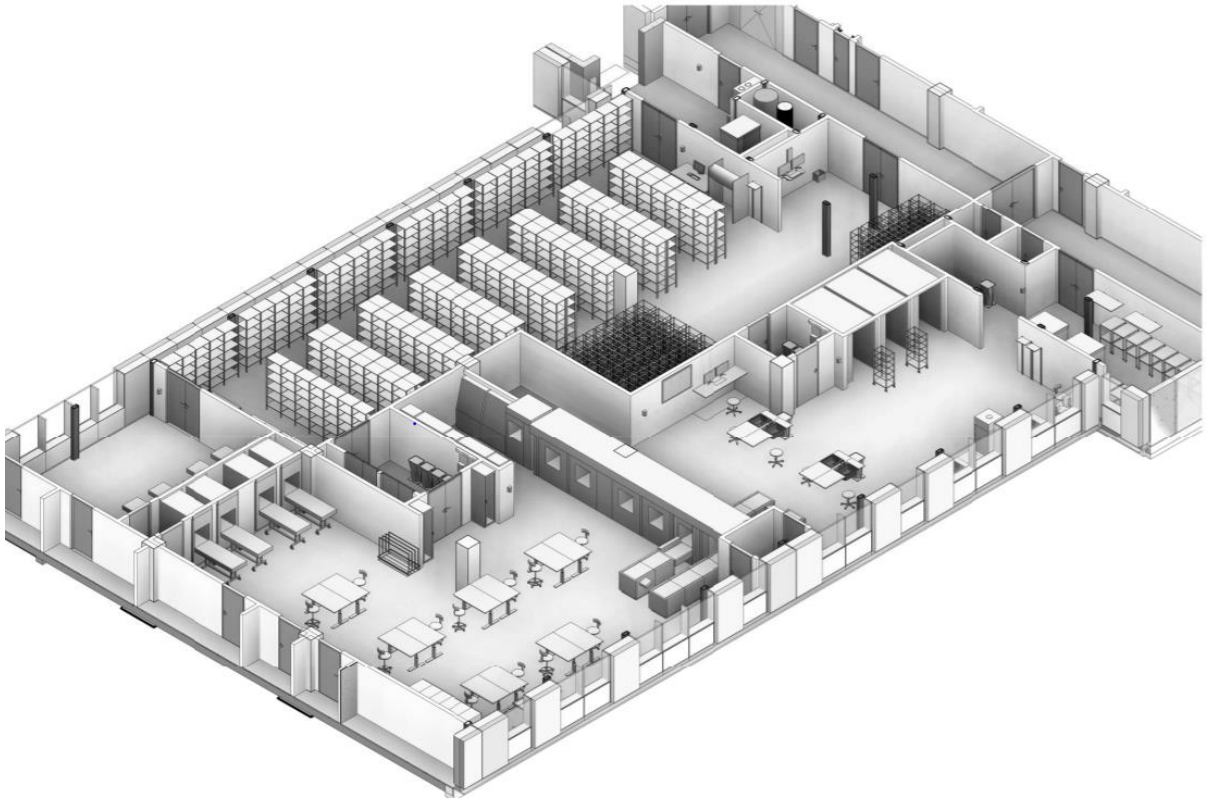

Figure 24: Preliminary design in 3D view

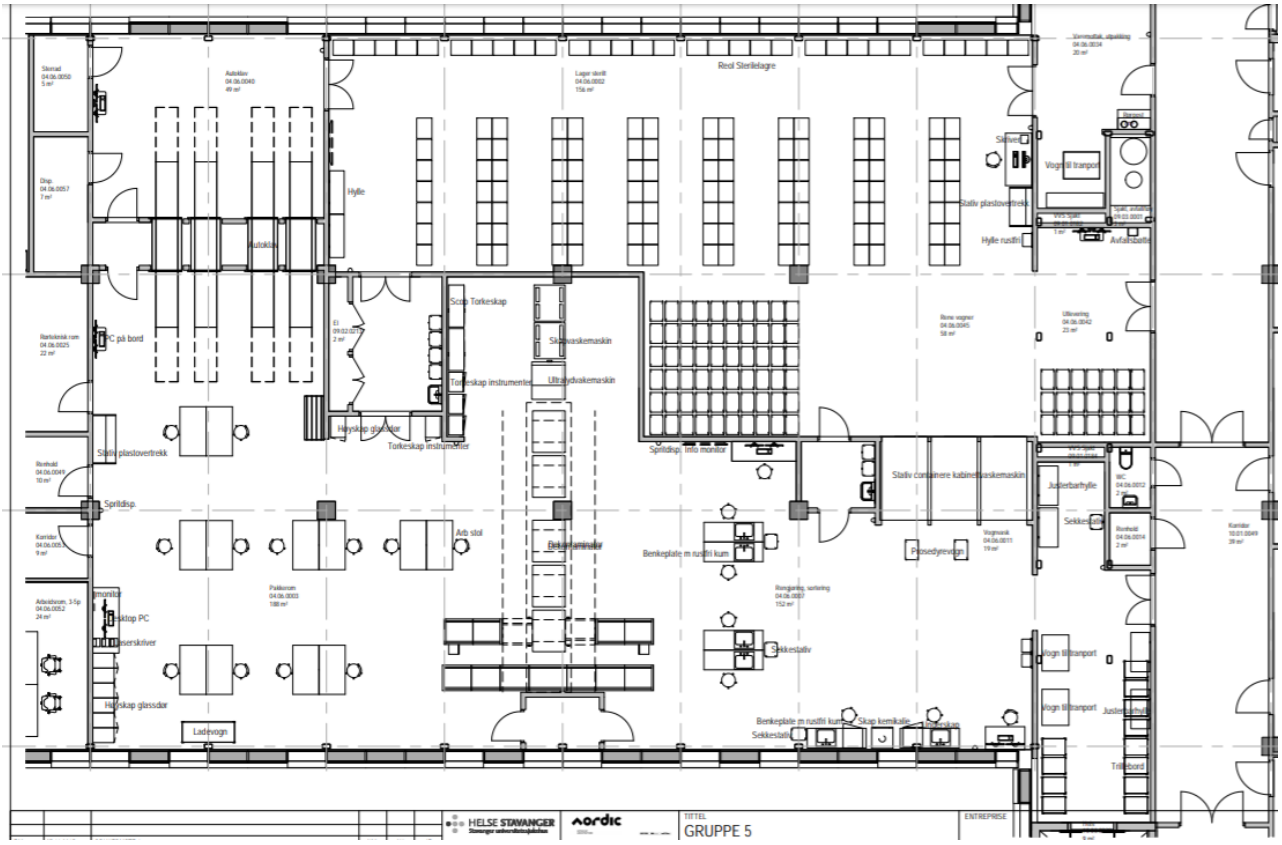

Figure 25: Preliminary design in 2D viev, provided by Architect Anne Underhaug

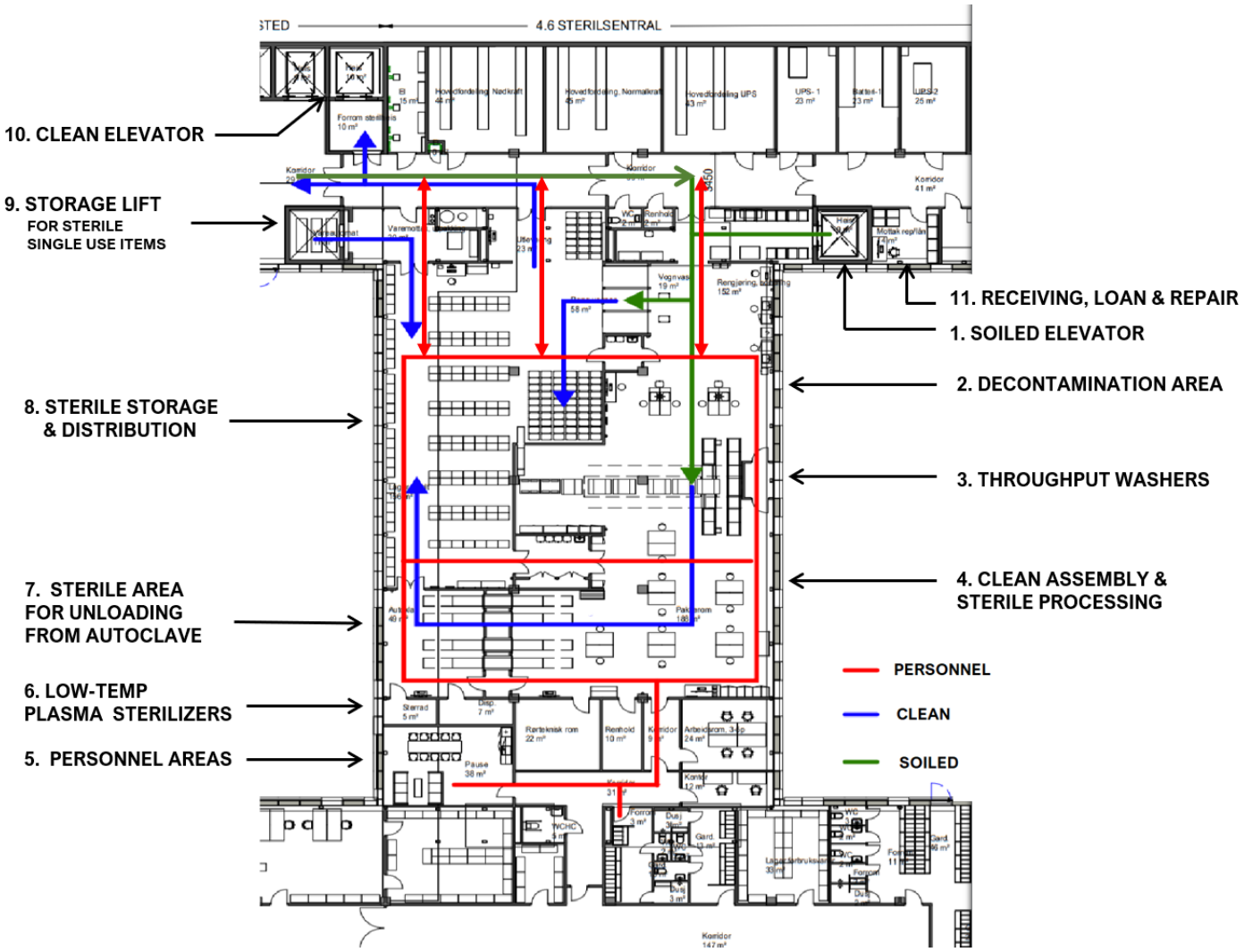

Figure 26: Preliminary design with Flow & Explanation

The red paths in illustrates the personnel flow, the blue path represents flows of clean or sterile equipment, while the green path represent the flow of soiled good.

1. **Solied elevator**: The soiled goods from the surgery department on the 3rd floor arrives thorugh the soiled elevator, while the soiled equipment from the remaining department arrive thorugh the corridor with the green arrow.
2. **Decontamination area**: Consists in a area where soiled goods and carts wait. Three throguhput washing machines for the carts is integrated in the wall between the decontaminated area and the clean cart storage in the sterile storage and distribution area. The reusable equipment is initially cleaned and sorted, before sent to machine washers.

3. **Thorughput washing machines**: A line of thorughput washing machines, most likely a combination of tunnel washers and regular washingmaschines is placed in the wall between the decontaminated and the clean zone.
4. **Clean assembly and Sterile processing:** Once unloaded from the washers the clean goods is inspected, sorted and packed, before placed ready for sterilization.
5. **Personnel areas:** Behind the clean & sterile zone there is areas for the personell, offices for CSPD management and some technical rooms.
6. **Low temperature Plasma sterilizaers:** There is a dedicated room for low temperature sterilizing by plasma, due to the fact that it produces quite a lot of noise.
7. **Sterile area for unloading from Autoclaves:** A dedicated room for the unloading and cooling of the equipment that has passed through sterilization. In this way the damp and heat from the unloading can be easily ventilated and seperated from the sterile storage.
8. **Sterile Storage & distribution:** This area will store neccesary sterile reusable equipment trays under specified environmental conditions. It will also store clean carts, and be used to pack proceure specific carts with both sterile reusable equipment and single-use sterile items.
9. **Storage lift of single-use sterile items:** A lift system for storage of sterile single-use equipment is planned.
10. **Clean elevator:** The clean elevator is used to send the finish packed sterile procedure carts up to the surgery department. The sterile goods to the rest of the departments is transported through the corridor as marked by the blue arrow, and on to their destinations.
11. **The receiving area for loan & repair:** A dedicated area is neccesary for the receiving of loan equiptment, new equipment and for equipment that is to be or have been repaired. This was provided after input from the SPD was given.

4.1.3 Perspectives on planning the new CSPD from the project group

The process of planning the new CSPD in SUS2023 has proven to be a challenging task, with many stakeholders and conflicts of interests to consider along the path of finalizing the design. To get a holistic view on the process of planning and designing the CSPD four different interviewees' perspectives are included. Their insight to the new CSPD functions, the planning process, its challenges and important decisions to be made along the way is included.

Kristin Gjersten is the current manager of the sterile department at Våland, she will also be the manager in charge of the new CSPD at Ullandhaug. Her perspective is operational and considers how the design will facilitate for a smooth workflow and working environment inside the CSPD. Anne Underhaug is the architect responsible for the physical and functional design of the CSPD, relative to the rest of the hospital. Ove Norstokke is the project manager in charge of overlooking the planning processes and acquiring the technical equipment required in the CSPD. Stian Refsnes Henriksen oversee the logistics concerned with organizing the CSPD as a sterile supply function. The subchapters will provide the perspectives of the project group in respective order.

4.1.3.1 Perspective of the SPD Manager

The Sterile Department Manager is one of the most important stakeholders for the CSPD project and have several wishes for the future department. A top priority is that the space provided for the CSPD is sufficient to provide a good workflow without bottlenecks. Imperative to providing this, is having a good quantitative foundation on the capacity requirements of the CSPD and getting a good idea on how the capacity requirements will be affected by the centralization of what today is quite fragmented activity. The CSPD manager has been involved in calculations, were data from T-doc have been used. The processed equipment was divided into categories based on surgical discipline or other functions. The volume and variation of equipment within each category were calculated and translated into number of containers and trays. The numbers of trays and containers were translated into machine and cart capacities. A forecast for year 2030 were included. It was however challenging to collect valid input for the calculations due to the fragmented nature of the sterile processing in the hospital today. Especially when it comes to all the equipment that has been washed at other locations in the hospital, such as in example the equipment of the anaesthesiologist that only requires washing.

In the sterile managers opinion, the design provided thus far is not optimal. This is due to several reasons, such as the fact that the flow is not entirely unidirectional when it comes to separating clean and sterile goods, an example is sterrad room where clean equipment must be brought through the sterile area with unloading of autoclaves. It is also inconvenient that the personnel must move through the department to get to the personnel areas, and offices. The office should preferably be placed near to the goods reception for easy collaboration. They are now on opposite sides of the CSPD. There is also general concern on the topic of whether the area dedicated to the CSPD will be sufficient to room the required activities, facilitate a good workflow and for storage of required equipment and material.

The sterile department manager has several wishes for the new CSPD, which is summed up in the following list:

- The CSPD design should facilitate for a logical flow of equipment and people, that doesn't interrupt the unidirectional flow from dirty to sterile.
- It should be up-to date and provide the required environmental condition required in a modern sterilization facility.
- All equipment trays should be standardized and stored in containers. Today some of the trays are "physician specific" meaning that it contains the preferred equipment, organized the exact way the individual physician prefers it for that specific procedure.
- A better priority system should be provided, that makes it easy to recognize what trays to prioritize next. The system could in example be a screen that provides real-time queuing of the waiting equipment, based on operation schedules, where rush orders would move to the front of the line and be alerted.
- Integration between operation scheduling and the tracking systems. It would be a great advantage if the required instruments were automatically booked once the operation was scheduled.
- A solid transport schedule and system for communication, to provide a smooth flow of goods and information inside and between the hospitals, seeing as transport distance will increase significantly for the departments at Våland.

4.1.3.2 Perspective of the Architect

Architect Anne Underhaug is specialised within hospital design and planning, with long experience within the field. She is hired by SUS2023 to assist in both global planning of the hospital and local and functional planning for specific areas such as the ORs and the Central Sterile Processing Department. Another important aspect of her work is how different rooms and departments should be placed relative to each other, in order to provide a logical flow of patients, staff and material within the hospital. The preliminary design is provided by Anne. This subchapter will give insight into thoughts behind the location and layout, as well as the design procedure and its challenges, from the perspective of the architect.

The main thought behind the **location** of the CSPD in the new hospital was to facilitate for close and effective collaboration between the CSPD and its main customer, the surgery department. In cases where the CSPD is not located next to the surgery department, the best solution is to place it right beneath and connect the two department with a dedicated clean and soiled elevator. Since all the heavy surgery will be centralized to one department, the choice of this elevator transportation system is the most convenient and effective. Another important aspect with this configuration is that it facilitates for a closed loop of sterile environment, a so called "green" sterile zone. The closed loop means that the risk of compromising the sterility of the equipment will be reduced and the equipment does not need to be transported in closed or covered carts, which reduces both time and waste.

As an architect, the starting point for the entire **layout** of the CSPD is to localize where the clean and soiled elevators is to be placed. Based on the location of these, the rest of the flow can be determined. However, the placement of the elevators in this case had to be determined based on the layout of the surgery department. The layout of the surgery department again, must be determined in relation to the global design and total flow of patients between the different buildings in the hospital, which are connected by the bridge system in the middle of all the buildings, as seen in Figure 17. The surgery department is divided into a patient side, and corridors on the other side that provides service functions to the ORs. Without going into the intricate details, the layout of the OR resulted in having to place both the soiled and clean on the same side of the surgery department, in the service area. This means that the layout of the CSPD, placed directly beneath it, must have a U-shaped layout. A more optimal layout for the CSPD would be one where the flow is straight from dirty to clean, in an I-shape. But this would require the dirty elevator to be on one side of the CSPD and the clean elevator to be on the other. Which is not preferable in the context of the rest of the building. One must therefore look

at the bigger picture and try to find the most optimal solution for the entire hospital's logistics. In addition to the U-shaped layout and the elevator placements, an area of approximately 900 square meters have been dedicated to the CSPD, based on the global design. The necessary placement of the building's pillars is fixed as well.

The focus has been on facilitating for the smoothest possible flow between the CSPD and its main customers, which is the surgery department. In addition, the maternity ward in building D have direct access to this service area and can in practise be linked to the same sterile loop as the surgery department. The ER, where urgent and stabilizing treatments are carried out are also in the neighbouring building. The configuration of the CSPD is not optimal for the flow for the materials that are not transported by the elevators. The receiving and dispatching area of the CSPD will be on the opposite side of the corridors leading to the other departments and the goods reception, so this equipment must take the detour around the whole CSPD before moving on to their destined location. But in the next construction phase, which starts after the completion of SUS2023, there will be built an additional building for day-surgery in direct contact with the E-building. This will drastically reduce the amount of equipment needing to take this detour. The distribution of material to the new building can be directly connected to the corridor with the receiving and dispatching areas of the CSPD. The planning horizon is therefore long-term, and the solution will be best fit for the final outcome rather than the temporary outcome of SUS2023.

As a functional architect Anne is involved with planning the workflow, inventory and equipment of the CSPD, within the given frames. In the process of making important decisions, the architect describes how the lack of specific information on what functions and tasks the CSPD is expected to carry out, has made it a challenging process. She emphasises how it would have been helpful with an official document stating the functions and tasks of the CSPD from the early phases of planning. Preferably signed and agreed upon by the important stakeholders.

When the first designs were provided, it was on the basis that the CSPD would do what the SPD does today. This was a wrongful assumption. It took time before it was communicated that the SPD dis not have a washing line, which it was expected that the new CSPD would have. Such decisions will affect the design to a great extent. Another issue that the project group is discussing today is whether there should be a dedicated flow to the equipment that is considered non-critical or semi-critical devices which are only to be washed and disinfected. If this task is to be included in the CSPD services, it must be considered in the design as well. It must be

organized in a way that allows a systematic return of this equipment to the dispatching area after washing. These decisions are not up to the architect to make. But the lack of precision on what the expected tasks of the CSPD is, makes the architects job much more challenging.

Another important design consideration is what capacity the CSPD needs to handle. If good calculations on the capacity requirements were provided early in the process, based on the agreed upon set tasks of the CSPD, the architect believes that it could influence the area provided to the CSPD. Which again could provide a foundation for more optimal designs. As it is today, there is worry that the area provided might not be sufficient enough for the future, seeing as it is not based on a clearly defined set of tasks and their capacity requirements. There is however still a possibility to move the personnel areas, as seen in Figure 26 to another location and expand the area of the CSPD.

There is room for improvement when it comes to the process of designing and planning the CSPD. The logistics at the CSPD is an extremely complicated puzzle. If there has been, from day one, a clear agreement upon the tasks and the associated capacity requirements of the CSPD, it would definitely provide better grounds for providing a design facilitating for the best possible functionality of the CSPD.

4.1.3.3 Perspective of the logistics manager

The logistics manager of the project is concerned with the logistics and organizational factors of the CSPD as an entirety. Sorting out the design and equipment requirement of the CSPD is not the goal of the logistics manager. The design and equipment will however be important tools to facilitate for the best solution in the end. With the goal being to deliver the best possible services, with a manageable amount of equipment and material in rotation.

He explains how service concept the new CSPD will be responsible for the entire sterile supply in the hospital. This means that the CSPD will be able to supply its customers with complete procedure specific carts. These will contain both sterile reusable equipment, sterile single-use items and the required clean equipment, such as the equipment of the anaesthesiologist. This approach is quite new to Norwegian hospitals and provides a complicated logistics puzzle. High coordination will be required between the staff of the CSPD, the OR and logistics workers. The CSPD staff will oversee the sterile processing and supply of reusables, while the single-use items will be handled by the logistics workers. The sterile department at Våland have already started preparing for this collaboration, by having logistics workers in the CSPD taking care of the logistics tasks such as replenishment and procurement.

In order to pull of the new service concept, the CSPD will be designed to incorporate a single-use sterile item storage, in the shape of a automated elevator dispenser storage. This storage systems will go through all the floors and utilize not only the area, but also the volume of the hospital. Since the price per square meter in the new hospital is so high that there will not be budget to provide excess in area or high levels of buffer-equipment, of neither reusable nor consumable. However, a levelled and smooth flow of material can reduce the need for buffer storages. But there will always be need for some buffer storages to not put the whole system out of balance when a surgery takes longer than expected, and it is planned to use the same equipment in the following surgery some hours later, in example. The required inventory levels will also depend on factors such as processing times of the machines and the capacity of staff available to ensure a continuous flow of goods through the process etc.

With regards to the **space** dedicated to the CSPD, everyone shares the same concern with regards to whether the areas provided are sufficient. The **capacity** required at the washing stations and sterilization machines is what he thinks will be the most dimensioning factors. A way to look at the capacity requirements is to look at the hours of highest activity during each day, and to dimension the processes to be able to handle this. SUS2023 has been in contact with the third part NIRAS, to provide capacity analysis. Based on historical data and processing times of the different equipment it is possible to calculate the necessary processing capacity at each stage of the process, to provide a levelled flow without bottlenecks, at least in the analysis. The real world is always a bit more complicated.

The logistics manager mentions several factors that is of importance in order to facilitate for a well-functioning logistic system. **Technology** is one of them. The success of the CSPD will be influences by the choice of equipment and machine but also by the **ICT-support systems** such as T-Doc, SAP and the operation scheduling tool. Another factor is to share and utilize the information provided by the ICT systems in a productive manner. Analysing the available information can help recognize behavioural patterns and provide important information for making managerial decisions and discovering potential system improvements. Jet another factor is the **human resources**. It is important to have the right people, with the right competencies, at the right place. The biggest time thief of the staff in the OR and the CSPD, is when they are put to do tasks that are not within their field of expertise, such as a logistics or cleaning task. In order to avoid this waste of expertise an important measure has been to dedicate secondary tasks of one profession to another profession who can merge the task into their primary tasks. In this way, the tasks are usually performed better and with more

willingness. Standardization of the **workflow** of the CSPD is also an important factor that will influence the process performance. Doing the same task, in the same way every time will reduce the chances of error and improve the efficiency of the task. The machines will also influence the workflow. An example is large washing chambers with a capacity of 20 trays vs a table-top washer with the capacity of 5 trays. The washing chambers have larger capacity, but there might incur waiting times in order to fill them up enough before a cycle is initiated. While the smaller tabletop washers does not have the same capacity but provides the possibility of more flexible and continuous washing. There must be a good balance in order to create a good workflow with enough capacity without too long waiting times.

Another strong trend in sterile processing is **automation,** to get updated on the selection the project group have had contact will suppliers Most of the automated systems are concerned with the tasks of transporting the equipment trays into the washing machines, from the washing line and to the packing area and from the packing area and to the sterilization machines. There are both pros and cons related to automating. It can free the workers from heavy lifting and make the processes more efficient. At the same time automated machines are noisy, can have breakdowns and it requires a large investment. It is not decided to what degree the flow will be automated yet. But it is important to be realistic on what the needs of the department really is. A fully automated production line will most likely not be financially justifiable with the scale of their production. But automation in smaller scale to relief the staff of some of the heavy lifts can be advantageous.

The **flexible long-term processing capacity** must also be taken into consideration when planning and designing the CSPD. The possibility for a need of expanding the processing capacity of the machines is taken into account. A possibility is to leave extra space in the walls where the machines are put through, so that in the future there is room to place additional machines there. However, expanding the capacity can also mean changing the machines with more space and time efficient machines, that will allow for higher throughput rates.

Planning for the future is a challenging task. The project group do their best to incorporate all known and predictable factors into the planning and stay on top of the market trends. **New medical procedures** are regularly introduced. The hospital wishes to provide new treatments to their patients, but that does not mean that the old treatments are excluded. It merely means that there will be an increase of required equipment in storage. These are factors that must be considered in the planning. The rapid medical evolvement may feel frustrating for the

supporting department such as the CSPD, which merely have to adapt to the changes as best possible. It is first when the support function is a proven bottleneck for the primary activities that it will be considered to update these functions. In order to adapt to the future developments, the biggest challenge will probably be acquiring the necessary financial funding to avoid bottlenecks and provide a smooth workflow. By exploiting the use of technology and the information it can provide, one can organize the workflow of the CSPD in manner that might compensate for any restrictions in space.

4.1.3.4 Perspective of the Project manager

The main purpose of designing the new sterile central in SUS2023, is to centralize all the functions that are carried out quite fragmented in the hospital today. The CSPD will provide the sterile services for both the old and the new hospital. Related to this comes quite comprehensive logistics. There are several challenging decisions to make in the process of designing the new CSPD. How much or less equipment will be required in the new sterile supply loop? What information should be shared, with whom and how? How should the new tasks be allocated?

The preliminary design provided today presents several challenges. The functions of the CSPD has changes a lot since this design was drawn. The CSPD is moving towards becoming both a washing central, sterilization central and a storage of consumables. This was not specified when the area was dedicated to the CSPD. There are uncertainties linked to whether the area is sufficient to incorporate all the "new" functions into its design. The only thing fixed is the placement of the elevators, the width of the CSPD, and the length. The length could however potentially be expanded by the personnel areas. The opinion of the project manager is that it is better to expand the area now, than having to split the sterilization functions again later due to space constraints.

The decontamination functions today are fragmented and carried out locally at the different departments. It has been challenging to figure out what parts to centralize to the CSPD and which to keep decentralized. Some departments have well-functioning routines when it comes to washing the equipment locally. The ER is dependent on having their equipment available at all times and would never consider sending it to the CSPD for washing. There has been discussion on whether the equipment used for the anaesthesia should be a part of the procedure specific carts delivered from the CSPD. In that case, it would be an advantage to incorporate the washing of this equipment to the CSPD. They have asked anaesthesiologists to provide

numbers on the equipment they wash, the frequency of use and their inventory numbers. When the numbers arrive, they will look into how and if this could be incorporated into the CSPD tasks. The CSPD must be able to process the demands expected from 2030, when all surgical activity is centralized, and the entire hospital will be finished.

Another questions that remains to be answered is how the tasks will be allocated once the single-use sterile item inventory is to be incorporated into the CSPD design. Not all deliveries from the CSPD will be in the form of procedure specific carts. There will also be department that merely require replenishment of some single-use sterile items. It must be decided whether these tasks will be handled by the CSPD staff or by active supply.

The new CSPD will also need to apply several supporting technologies. Today, the IT systems used are T-Doc for tracking and documentation of workflow, Sap S/4 Hana for procurement and inventory control of the single-use items, and the operation schedule program used by the departments. Deciding what information that should be stored where is challenging with many systems to relate to. In the new CSPD it would be advantageous digitalize many of the operations that require a lot of paperwork today. Packing and signing of the equipment based on a digital solution rather than on paper would save time and waste. A solution for monitoring the progress in the OR would be helpful for the staff, so that they know when the next procedure carts should be ready. There are also discussions on to what degree the new CSPD will use machines and robots to relief the CSPD personnel from some of their tasks. This is something than would influence the design and layout of the CSPD.

4.2 Case description - St. Olav University Hospital

St. Olav University Hospital. St. Olav is a public hospital located at Øya in Trondheim. It was built in the period from 2005-2013. The hospital serves as a university hospital for the population of "Mid-Norway". The Hospital has 746 patient beds for general treatments. In 2018 the hospital treated 37 834 inpatients, 17 263 outpatients and 123 639 polyclinical patients (Helsedirektoratet, 2018). In a forecast developed for the period from 2015-2035, the demand is estimated to increase with 46% for polyclinical consultations, 23,6% for inpatients and 38,6% for outpatients (Sykehusbygg, 2017). However, the macroeconomic picture indicates that the hospital must face this challenge, without proportional increases in budget, staff or space. This will require comprehensive efficiency improvements regarding both employees and resources.

The hospital consists in six clinical centres. These are the Emergency & Cardiothoracic centre, the Gastro centre, the Woman & Child centre, the Mobility centre, the Neuro centre and the Knowledge centre. In addition, there is the Laboratory centre, the Supply centre, the Administrations centre and the Norwegian brain centre. 22 The hospitals seven floors (U1 to 6), are systematically divided according to activities. The basement floor consists of the technical areas, the CSPD, goods reception, cleaning functions, wardrobes and tunnels between the centres for distributing goods, the distribution is mainly carried out by AGV. The polyclinics are based on the first floor, and the second floor is where the ORs are placed.

4.2.1 The CSPD

The Sterile supply function at St. Olav Hospital centralized. The CSPD is located at the basement floor in the south wing of the Emergency & Cardiothoracic centre, as can be seen in Figure 27. General information is summarized in Table 8.

Table 8: General Information about the CSPD at St. Olav Hospital

Operating hours:
24 hours a day from Monday 7 AM – Friday 10 PM
Saturday & Sunday: 8 AM to 6 PM
Shifts: 3-shift system at weekdays.
Day-shift: 7-12 employees (12 at Fridays)
Evening-shift: 14-17 employees (9 at Fridays)
Night-shift: 4-5 employees
Employees: 73 in total
Full-time employees: 43
Substitute employees: 30
Processing Lead times
Regular: 24 hours
Priority: 14 hours
Rush orders: ASAP

Figure 27: Location of the CSPD at St. Olav hospital. (stolav.no)

The CSPD serves all the hospital departments; operating rooms, polyclinics and wards with the required sterile reusable equipment. The orthopaedic department and operating rooms are the CSPDs biggest clients, with a share of 30% of the processing volume. The sterile single-use items are stored at the central storage at Heimdal and in decentralized storages in the departments. The sterile reusable equipment however, in the form of trays, containers and equipment, is only stored decentralized in their representable departments. The distribution of the sterile goods between the CSPD and their customers departments is done by the hospitals AGV system.

The CSPD have 73 employees, considering both full-time and substitute employees. The work schedule is divided into three shifts; day, evening and night. In weekdays the CSPD is manned 24 hours a day. In weekends it is manned from 8 AM to 6 PM. During the shifts, the employees rotate between the three zones of the CSPD. This is linked to HMS, ergonomics and keeping all the processes fresh in mind. The impact from the work that requires repetitiveness and heavy lifts is therefore moderated by rotating between tasks. During shifts the employees can also be moved to where the capacity needs are most pressing.

The layout & workflow of the CSPD

The layout of the CSPD at St. Olav University Hospital is provided in Figure 28. This subchapter chapter will provide an explaination of the layout and the associated workflow.

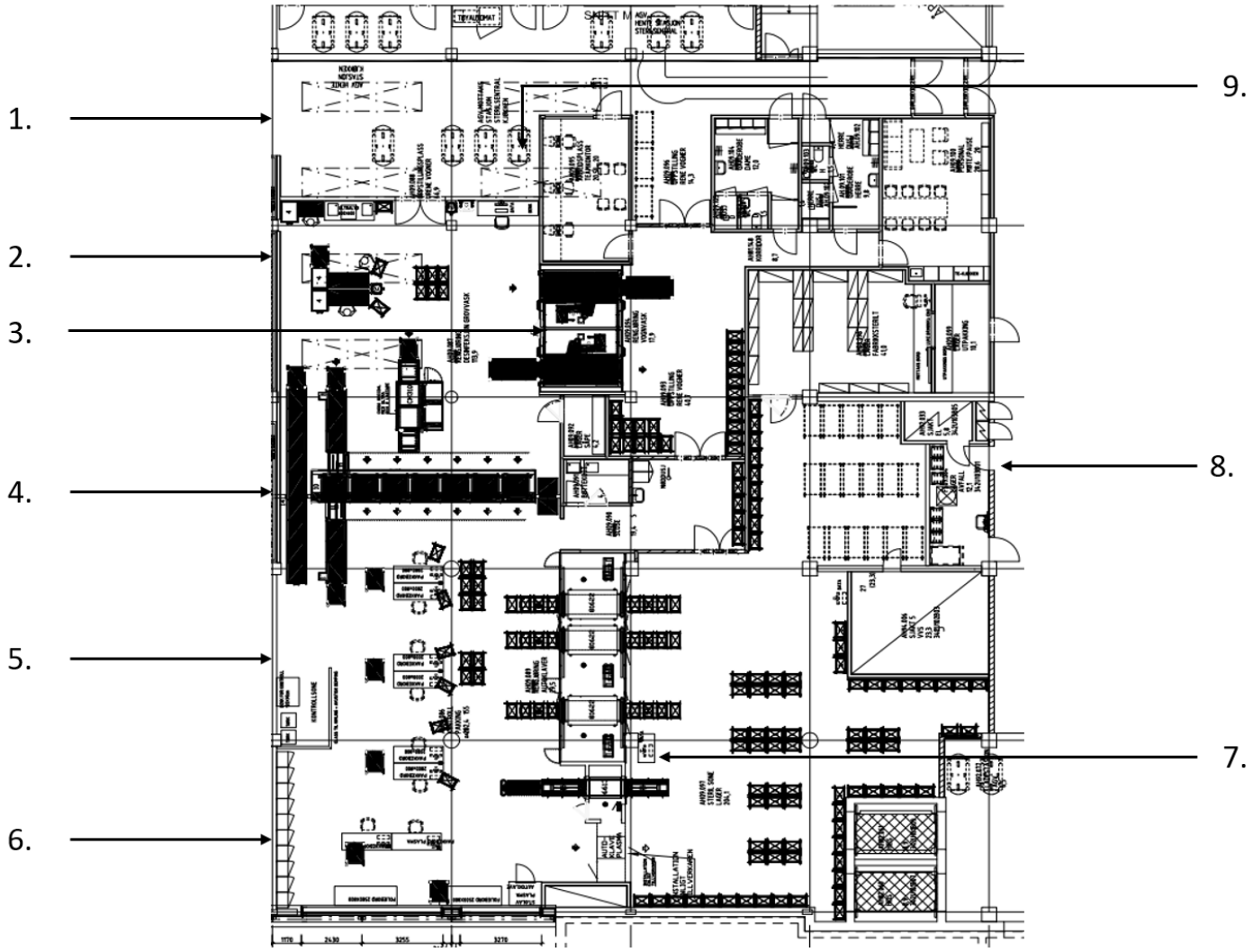

Figure 28: The layout of the CSPD at St. Olav

1. The soiled equipment arrives by AGV and wait outside of the Decontaminated zone.
2. The carts with equipment are brought into the decontaminated zone. And the equipment is unloaded from the carts and washed either manually, by ultrasonic washers or by one of the six table-top machine washers. Or a combination.
3. The soiled carts are sent through the one of the two cart-washers and end up in the clean-cart storage outside the sterile storage.
4. The reusable equipment passes through to the clean area, either through the throughput washers, or through a hatch if manually cleaned. Here it is first cooled down.

5. In the clean zone, equipment is continuously inspected, sorted, assembled and packed based on orders and their priority status. Most of the equipment is processed at the different workstations which are dedicated to the different surgical disciplines. Some equipment trays are not arranged containers and require packing in non-woven textile wraps. There is a workstation for this.
6. Other equipment is not arranged in trays but packed as individual equipment. This equipment is routed out to the side to its own workstation.
7. Once packed, the equipment is placed in carts before sterilization. There are four autoclaves and two small low-temperature plasma sterilizers. The large autoclaves have automated loading and unloading, these must load four carts of equipment at the time. The sterilization takes 1h 40 min with the large autoclaves, and approx. 1 h with the plasma sterilizers.
8. On the other side, the equipment is cooled down in the sterile storage and processing zone. It waits there until issued or placed is placed either in the centralized storage or sent directly to the decentralized storages. Most equipment is stored decentralized. It is mainly the orthopaedic and eye-surgery department that have shelves with centralized storage.
9. The equipment is sent by AGV to the departments. Where it is either placed in storage or used immediately.

4.2.2 The sterile logistics loop at St. Olav Hospital

The material and information flow of the sterile logistics loop in its entirety is illustrated in Figure 29. The distribution to and from the hospital departments is by AGV. There is also a pneumatic tube system with dedicated dispensers for transport of single sterile equipment. Little equipment is kept in the storage at the CSPD, the largest share is sent to the decentralized storages of the customer departments, or straight to the OR. Before the equipment is utilized a pre-operation check of the equipment is done to make sure the required equipment is delivered and that all is in order. The equipment is then utilized in surgery and checked again post-operation before it is placed outside the OR, ready for return to the CSPD.

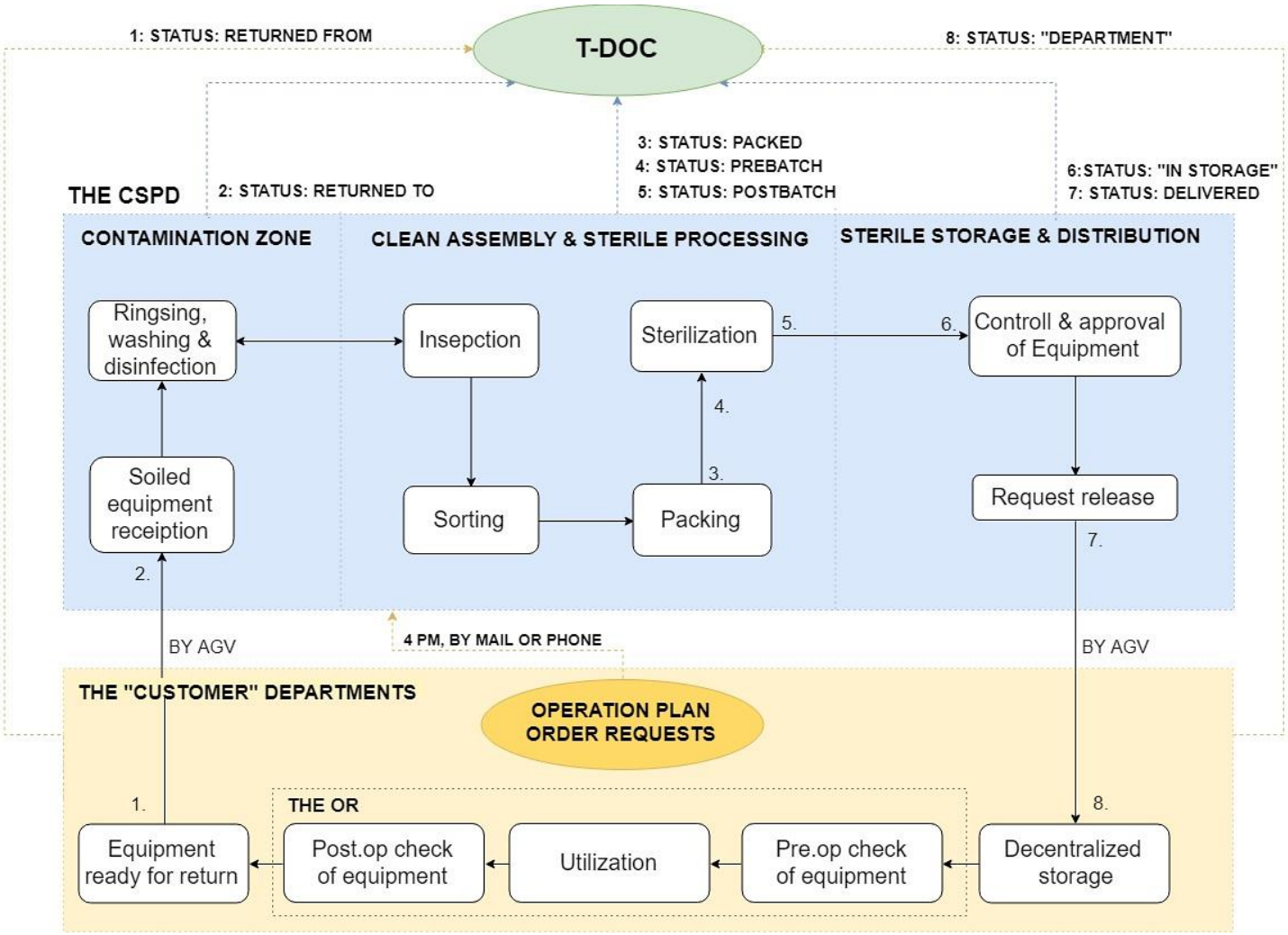

Figure 29: The Loop of Sterile reusable equipment at St. Olav Hospital

IT & Information flow

The IT-system applied to track and document the flow of sterile reusable equipment through the sterile logistics loop is called T-Doc. This is a well-known IT-system especially designed for sterile goods management. The system keeps track of where in the sterile logistics loop the equipment is, based on the last place it was scanned. It keeps track of activity numbers, processing times and documents that the equipment have been through the necessary activities before it is utilized in treatment. When the barcode of the trays is scanned in the packing station, T-Doc also provides instructions and descriptive pictures on the assembly and packing procedures of each tray. Even though there is an integrated function for electronic order-placement in T-Doc, this function has not yet been implemented at St. Olav.

With the use of handheld scanners and barcodes, the equipment is manually scanned at several stations in the sterile supply loop, as illustrated in Figure 29. When the soiled equipment arrives in the decontaminated zone it is scanned into the T-DOC system as "returned". In the clean zone, the equipment is registered in the T-Doc system when packed, when ready for sterilization and after sterilization. Once it is finished in sterilization it is cooled down in the storage and distribution zone. Even if it is only temporarily kept there it is registered as "In Storage" in T-Doc. Once the equipment I sent to the departments it is registered as "delivered". Once the equipment arrives at the department it's status is updated to the name of the department location. It is however not registered when the equipment is taken from the decentralize storages and in utilization. No status is provided until the equipment has been used and is registered as returned from department. Inventory tracking in the decentralized inventories have been a wish from the CSPD side, but the department employed have not wished to implement such as system. Such systems lead to extra work in a workday that is already stressing enough. Scanning all equipment in and out of storage requires precision and unless this is done consistently, the inventory levels would not be correct anyway. Wrong inventory levels may be more dangerous than none.

Order placement & priority status

The hospital departments are utilizing manual requisition forms to list the requirements for the next day, and preferably at what time they need it. The forms are sent by mail to the CSPD within 4 PM each day. The emergency department can order within the same day, this is often done by phone.

The equipment is processed according their priority status:

"Rush-orders":	Rush-orders are the highest priority and is to be processed as efficiently as possible. Occurs if a trauma arrives at the ER and the required equipment is not ready in sterile storages. This is not often.
"Priority-orders":	Is to be processed within 14h. Often equipment with high utilization rate.
"Regular-orders":	Have a lead time on 24 h from the orders arrive, and until it is to be finished in processing.

As long as the 24 h and 14 h timeframes are being fulfilled, orders of same priority status are prioritized based on the delivery times. The orders that are needed already 7 AM the next morning are prioritized before the later deliveries. As it is today, the only guarantee the departments have at having their orders delivered on time, is if they send the equipment to the CSPD in good time before it is needed in surgery. Many departments are challenged with frequent changes in surgery schedules and accompanying equipment requirements, that makes it hard to place orders longer in advance. Monday and Tuesday are however fast-track days at the CSPD. Emergency surgery excluded, these are the days when the most comprehensive surgeries are carried out, and the demand on the CSPD is on its weekly highest. The equipment needs for these days can often be placed longer in advance.

4.2.3 Assessment of current process design of the CSPD

This chapter will prove insight to different aspects of the current process design. The current solution and design of the CSPD at St. Olav Hospital is explained as bearable, but not optimal. When the CSPD of St. Olav was finalized in 2009, the room planners and CSPD management were given a physical restraint in the form of a designated area in which they had to adapt the department. The long-term capacity calculations were based on historical numbers on surgery and procedure activity in addition with other known factors such as demographic changes in the area etc. A forecast was provided for a period of 20 years ahead in time and used as capacity input. Now, 10 years later it is the opinion of the CSPD management that the department already are working at the maximum of its capacity to make the ends meet, and sometimes they fail to. There are shortages in both machine capacity and space in the CSPD. This is reflected through the fact that they are getting complaints and experiencing issues with delivering within the promised lead time. There is never not a line of work to be done, and it has a draining effect on the employees. In the future, they will need to think different to make the system more robust.

"A better solution and design would most likely have been provided if the department had been designed from the inside out, to facilitate for the required quality and functionality of the department before the physical restraints were given. It is first when you plan from the inside and out that process optimization can be achieved"- CSPD manager

Location

The most important criteria for the location of the CSPD at St. Olav:

1) Easy access to the AGV system: All the centres and departments are supplied by AGV. The AGV systems travel underground and move vertically by elevator as well. Therefore, contact with the AGV system was essential, but it does provide some flexibility in regards location.

2) Closeness to customers: It is a definitive advantage to be in short distance to the customer departments. Moving the CSPD further away from the hospital would make the supply loop longer and require better planning and more trays of equipment to make up for longer travelling distances.

Capacity

As explained in the introduction of this chapter, the CSPD experiences capacity issues both in machine capacity and space restrictions in the department.

"It is worrisome that the distance in-between the clinical practise and the operations at the CSPD only seems to be increasing. If the operations at the CSPD are to remain sustainable, the capacity of machines and workers need to increase proportionally to the rate at which the clinical practise are escalading their efficiency and patient treatment rates."

Matching the processing capacity with the demands of the future will be important. A solid forecast tools, in addition with an objective and qualitative way to calculate equipment need and the right balance in machine capacity and required employees can be decisive for having a functioning CSPD.

A good starting point when it comes to deciding on necessary capacity of a CSPD is calculating the demand for trays and equipment. The physicians know the equipment needs for the different types of surgery. Historical procedure statistics in combination with forecast for the coming decades can give a good indication of the future amounts and mix of surgery. Based on these inputs, accumulated future processing capacity need can be calculated. Then finding the correlation between the daily processing needs and the required amount of employees would be key.

"One cannot plan a new sterile department today without taking into account forecast's on expected demand 20-40 years into the future."

Bottlenecks

The biggest bottleneck of the CSPD processing at St. Olav is the washing process in the decontaminated area. It is always filled up with equipment and carts waiting to be washed. For the future they believe in thinking in the form of having "washing halls" instead, with more machine capacity and storage capacity for both the carts and equipment. The waiting carts could be placed inside the washing hall to provide better overview of waiting equipment and free the CSPD employees from having to move outside of the CSPD to get the next cart in line. Today the hallways outside of the decontaminated zone is being filled up with carts waiting. This becomes a very apparent and visually explicit bottleneck, that have a negative psychological effect on both the staff of the CSPD and their clients.

Another time-consuming step is having to re-wash the equipment that does not pass inspection. The re-washes are often caused by poor loading capabilities of the washing machines in combination with the complex shapes of the equipment, that makes it challenging to clean everywhere. In the future they wish to avoid re-washing. There are also trays that need to be split in the washing step, because the equipment requires different wash methods. These trays are a bit of a hassle when it comes to optimizing the efficiency.

There can also be bottlenecks other places in the sterile loop, such as up in the departments. The people working in the surgery suites have busy working days. It is often that the soiled equipment is not brought down to the CSPD once it is finished in utilization. Often the personnel wait until they have filled an entire cart before they send it down, leading to typical rush-hours and bursts in the arrival patterns at the CSPD. This could be improved by for example having automatic notifications to alert the logistics employees (active supply), that finished soiled equipment is ready to be retrieved from the departments. As it is today, the active supply employees usually check every once in a while, but it can often happen that they check at 11 AM, when the soiled equipment is ready at five past, and then they don't check until 12.30 again, so that equipment often have waiting times that could have been value adding instead if the personnel was only alerted. Re-organizing the return process could also be beneficial. Today, the operation nurses place the soiled goods outside the surgery suite after use, but active supply needs to pick up and bring the carts to the AGV stations for return. One link, and a lot of waiting time for the soiled equipment could be eliminated by having the operation nurses place the used equipment directly onto the AGV stations. This could facilitate for a smoother arrival pattern at the CSPD as well.

The inventory of reusable equipment

When the CSPD was initially planned, the thought was to implement a central sterile storage in the CSPD. The hospital departments were given 23 million NOK to buy equipment and trays. However, 17 out of the 23 million NOK were prioritized otherwise. After spending 6 million NOKs on equipment it was stated by the hospital department that "this is enough". This has shown itself not to be true, in the CSPD's opinion. The limited equipment inventory resulted in decentralized storages in the departments, since there was not enough equipment to maintain a central storage.

As the CSPD managers sees it the entire order and deliver process would be less complicated if orders could be drawn directly from a buffer storage instead of having to process on order.

"If the hospital had sufficient volumes of equipment, they could have managed with only one decentralized acute storage, the rest could be kept in centralized storage at the CSPD. This would provide a better overview on the accumulated inventory status, and shortages would become more obvious."

The CSPD manager explains how decisions regarding the necessary inventory of equipment need to consider the accumulated demand put on the CSPD. There are definite conflicts of interest between the hospitals departments and the CSPD. The departments are in charge of ordering the necessary equipment for their practise. Due to tight budgets and tough priorities, they do not wish to spend any part of their budget on "extra" equipment. The CSPD is equally under immense pressure to deliver the required equipment to all the departments within the specified lead times. But there are shortages in both machine capacity and reusable equipment, and the hospital departments are complaining that they don't get the equipment in time.

"*The departments argue that the CSPD is not efficient enough, while the CSPD argue that they don't have enough processing capacity and that the delivery issues could be avoided if the departments had more equipment in rotation*."

Today, the throughput rate of patients for some of the medical procedures are increasing, due to efficiency improvements of the procedures. These "quick-fix" surgeries are being moved from the OR to the polyclinics. Some of them last no more than 10 minutes, meaning that 40-50 operations can be carried out in a day. This requires high throughput rates in the CSPD. But with the 24h lead-time the polyclinics have seen the need to supplement their procedure trays for these procedures.

"For some of the procedures, the sterile processing needs are increasing in the direction of a mass-production."

Introduction of new equipment

New reusable equipment is frequently introduced at St Olav Hospital. Due to new medical procedures or renewal of the different procedure trays. The changes provide equipment that is easier to use for the physicians, but often harder to clean for the CSPD employees. The new equipment rarely requires changes in the processes at the CSPD, but it does however require new training of the employees.

Due to the frequent replacement and renewal of equipment, they believe that the future is more consignment equipment. Seeing as the equipment is getting more and more specialised, they believe that in the future the hospital will own fewer and more standard trays and have the specialized trays on consignment. Today they have some trays that are held in consignment with the supplier, but this is mainly orthopaedical trays. Both equipment owned and on consignment are sterilized in the CSPD.

4.2.4 Future development of the CSPD

There are many implications when it comes to how the CSPD will need to develop in the future. Both with regards to external influence, internal influence and in order to maintain sustainable and efficient operations. One of the biggest challenges is the fact that the demands are expected to keep increasing, especially in the polyclinics. External factor that might influence the demands are the political picture and decisions such as**;** municipal merging, the distribution of patients and specializations between the different hospitals, new hospitals and acute functions or removal of existing hospital functions. But as one of Norway's biggest University Hospitals, St. Olav is sure of one thing and that is that they must prepare for an increase in patients. The CSPD will also need to prepare for the future trends in medical care and its accompanying equipment. The use of flexible endoscopes in surgery is steadily increasing. Disinfecting these is a function that has remained a decentralized function handled by the operation nurses. But with increased use may lead to centralization of this practise as well. It will likely be more specialized and robotic surgery, with more specialized equipment that is held in consignment with the suppliers due to frequent changes in equipment.

Automation and technology will also be highly relevant tools in the future CSPD. In order to improve the visibility of information and optimize the efficiency of the processes at the CSPD

digitalization and IKT systems will be important. Real-time tracking could be helpful in the purpose of mapping, planning and continuously improving the workflow. It could also share information on the whereabouts and status of the equipment with the customer departments to provide them with the security of knowing where in the process the equipment is at all times. Transportation, lifting, loading and unloading of the trays into machines are among the tasks at the CSPD that have great potential for automation. Today, the loading and unloading processes are automated both for the washers and the sterilizers. The CSPD management of St. Olav believe that serialization and standardization of the processes will be more efficient than parallelization based on their differences. They believe in using the manpower where it is required but let the rest of the process be handled by machines.

"The more people involved with the sterile processing, the more possibilities of human error. The process needs to be as standardized as possible, allowing little room for deviations. That is why the future is within automation of the sterile processing."

The functionality of the CSPD will only become increasingly important in the future, and there is a need to plan from the inside out. If freed from the chains of budgets the management of the CSPD would like to; expand the area of the department and the machine capacity, especially in the decontaminated area. Then, the inventory of equipment trays would have been supplemented quite significantly to make in possible to produce to stock. This would require proportional increases in staff and storage space. There is also a wish to hire more technicians who are specialized in sterile technique. In the future it would also be interesting to incorporate more robotics into the sterile processing. With the goal of ultimately having an automatic processing line, were machines handle the large share of the operations, and the workforce can be dedicated to only the necessary operations. But in real life the thoughts of automating the CSPD at St. Olav Hospital is in the far future. The CSPD is not the top priority of the hospital, and the processes of getting funding to make changes are slow. The priority the coming years will be to improve the processes within the current physical constraints. Reducing unnecessary steps and minimizing the impact of bottlenecks by mapping the flow are examples of measures to take. This will help to some degree, but in the future, there might be a need for the CSPD to move outside the hospital walls, if the required area cannot be provided within. There might be needed to build a new department faster than expected, or worst case spitting the production, and have 30% be produced at the Neurocentral.

5. Findings and Discussion

This chapter will present and discuss the findings of the thesis. First the findings of RQ1 will be presented and argued for. A summary of the findings is provided. Secondly, the findings of RQ2 will be presented, a suggested systematic design procedure for process design at the CSPD is provided and lastly and the chapter is wrapped up with a discussion.

The findings are based on the theoretical background from chapter 3 and the empirical background from Chapter 4. Chapter 3 contributes with insight into general theory on process design and with theory and literature directly related to the specific processes and logistics of the CSPD. Chapter 4 provides valuable insight through two case studies. The case at St. Olav provides input on the operational processes and performance of the CSPD as a finished product, and how it is affected by the design decisions made over 10 years ago. While SUS2023, the project involved with planning the new hospital and the accompanying new CSPD in Stavanger, are in the process of making important design decisions. Valuable insight is provided into important decisions, how they are being made and what challenges the project group have been faced with in the design process.

RQ1: What are the design decisions involved when designing the processes of a Central Sterile Processing department?

When designing the processes of the Central Sterile Processing Department there has shown to be many design decisions involved. The activities involved in the process design of the Central Sterile Processing Department, are in many ways comparable to the general process design from operations management, which is explained in Chapter 3.1 and illustrated in Figure 3. The decisions can in the same way be divided into the strategical and operational design decisions. However, the CSPD is an intricate and specialized process, which requires some extra consideration in its process design. The main design decisions and their specific content for the process design of the CSPD are provided in this chapter. Each decision, it’s content and it’s reasoning for being an important design decision will be discussed based on both the literature from chapter 3 and using the cases provided in chapter 4.

The strategical design decisions of the CSPD:

I. Location – Where should the CSPD be located?

In literature the choice of location is said to have an impact on the service level and costs. It is also emphasised how location is a highly strategical design decision, that is not easily redone. (Kobus, 2008) and (van de Klundert et al., 2008) explains how the Central Sterile Processing Department, which primarily supports the surgical suite, should be placed central to the surgery department(s) within the hospital. It is therefore often located close to, below or above it the Operations rooms. Though (van de Klundert et al., 2008) argue for utilizing the valuable space next to the OR for primary care and cure, rather than secondary processes, and thereby argue for locating the CSPD below rather than next to the OR.

At St. Olav Hospital the CSPD is placed on the ground floor beneath the emergency and cardiothoracic centre, next to the movement centre where orthopaedic surgeries are carried out. In this way it is close to where the most urgent and some of the heaviest surgeries are carried out. The hospital is arranged in several individual clinical centres, and surgery is performed in most of them. All centres are however tied together by an underground transportation network, where the AGVs distributes most of the sterile equipment in closed carts. That is why the main criteria for the location of the CSPD was easy access to and from the CSPD with the AGV systems. The AGV system provided flexibility whit regards to the exact position of the CSPD but placing it in the underground made the most sense. The AGV system is not as effective as manual transport, which is used in rush-cases, but it has freed the employees from many logistical tasks that before served as a distraction from the primary care activities. If the CSPD in the future where to be moved outside of the hospital due to space restrictions, it would make the supply loop longer, and in order to compensate for longer travelling distances there will most likely be necessary to have more equipment in rotation at St. Olav Hospital.

At the new CSPD in Stavanger Hospital, the location is already set. All the heavy surgery will be centralized to one surgery department in the new hospital. With the ER and delivery rooms for birth located close to the surgery department. The architect explains that when there is not room to place the CSPD next to the surgery department, the next best thing is to place it right underneath. Therefore, the CSPD will be placed on the ground floor beneath the surgery department in the 3rd floor. The two departments minimize the distance between them by having dedicated clean and soiled elevators between them to distribute the sterile medical goods. Another benefit from this arrangement is that it creates a closed loop of sterile goods, were

equipment can flow between the CSPD and the surgery department without closed carriages or extra coverage, since the environmental and hygiene requirements are the same inside the loop. This reduces risk of contamination and waste generation. The deliverances to the other departments are however not a main priority, and there will be some inconvenient distribution routes for the equipment going to the other departments, at least until the next building step is finished in 2030.

The location is an important strategical design decision, which is closely knit to both the means of transportation and to the relative locations of the CSPDs' main customers. The main customers have been identified to be the surgery departments, and especially the orthopaedic surgery-discipline. The transportation modes can be both manual and automated and must be adapted to the vertical and horizontal travel distances of the system.

II. Capacity – What are the long-term capacity requirements?

Strategic long-term capacity decisions from operations management are, as explained in chapter 3.1.1, concerned with deciding the appropriate size and capacity of each part of the supply network. In order to do so it becomes important to find the correct balance between long-term capacity and long-term demand. Such decisions require forecasts of demand over a longer time horizon and converting the demand into capacity and space requirements. It also entails deciding upon the degree of flexibility to incorporate, which is related to the degree of demand uncertainty (Slack, 2013; Stevenson, 2014).

The strategic capacity decisions of the CSPD are mainly concerned with finding the required capacity and size of the sterile processing department as well as the storage capacity. This decision has therefore been split in two.

II.I Size and capacity requirements of the processing department

(WHO, 2016) explains how the space and capacity requirement of the CSPD will depend on the demand placed upon it. Externally there can be many influential factors on the long-term demands, which is out of the control of the hospital. Locally, in the hospital the demand will depend on factors such as the size of the hospital, the number of beds relying on the department's services, the treatments and surgical disciplines offered by the hospital, average surgery amounts and their characteristics, the operating hours of the sterile department and number of employees per shift. Table 5 provides an overview on space considerations and

equipment gathered from literature. If applicable to the individual CSPD, these concerns should be considered when deciding the size and capacity of the individual zones of the CSPD.

When the capacity of the processing department at St. Olav Hospital was calculated before it's initiation in 2009, it was based on half a year of historical numbers on surgery and procedure activity, and a forecast 20 years ahead in time were included. Now, 10 years later it is the opinion of the CSPD management that the department is already a working at the maximum of its capacity to make the ends meet, and sometimes they fail to. This is reflected through the fact that they are getting complaints from the customers and at times experience issues with delivering within the promised lead time. The main reason behind these challenges is said to be the shortages in machine capacity and space experienced in the CSPD. And seeing as the hospital don't have much buffer storage of reusable equipment, the CSPD is very dependent on having enough machine capacity. In cases of machine breakdowns, which happens every now and then, the system is easily put out of balance. The entire department is described as too small by both the management and its employees. In periods of high demand there is almost not space to move around in the clean department. The decontamination area is however explained as the biggest bottleneck of the CSPD, also due to shortage in machine capacity and space. Additionally, poor loading capabilities of the washing machines leads to too frequent need for rewashing equipment. This adds on extra demand which were not accounted for in capacity calculations and postpones the delivery times

The capacity shortages underline the importance of providing good forecasts, though understandable that this is an intricate task. The management of the CSPD believes that with the combined knowledge of the physicians, the CSPD management and the right documentation, it should be possible to provide good input on surgical equipment demand and translated this into machine capacity using good analysis tools. The primary activities at St. Olav hospital have increased both in volume and variation, and it seems as if the primary activities are advancing in a faster pace than expected. The CSPD argue that if their operations are to remain sustainable, the capacity of machines and workers need to increase somewhat proportionally to the rate at which the clinical practise are escalading their efficiency and patient treatment rates. On the other hand, it is natural that the primary activities of the hospital are prioritised in the budgets. The supporting activities are often not prioritized before it becomes an apparent bottleneck for the primary activities.

When designing the new CSPD in Stavanger Hospital, the top priority of the CSPD manager is that the new department has the required capacity and space to allow for a good workflow without bottlenecks. All participants for the project group share the same worry on whether the area dedicated to the CSPD is big enough. The area requirements will depend on the capacity requirements. Imperative to achieving a CSPD were the long-term capacity matches the long-term demand, is to have good input data on the expected demand, that is correctly translated into capacity requirements. The logistics manager believes that the capacity required at the washing- and sterilization machines will be the most dimensioning factors.

There have already been carried out some calculations based on historical demand and input from T-doc, with a forecast for year 20230 included. But two main challenges have presented itself in the process. The lack of clear definitions on what functions the CSPD was going to have from the start has resulted in misunderstandings and extra work. The other challenge is to collect valid input for these calculations, due to the fragmented nature of the sterile processing in the hospital today. Once a clear definition on what the functions of the CSPD is in place, new demand input will need to be gathered, and another analysis on capacity will be carried out by the third part, NIRAS. And with the new capacity numbers from the analysis, the chosen supplier must be involved in translating the capacities into machine and equipment needs and a new design must be worked out which is better adapted to the capacity requirements of the future.

When deciding the size and capacity requirements of the sterile processing it is important to incorporate some flexibility in the long-term capacity. If there is enough space in the walls where the machines are put through, there could be included space where additional machines can be installed in the future. Another mean for expanding machine capacity is to replace the machines in the future, with more efficient machines that allows for higher throughput rates.

The capacity of the sterile processing is of upmost importance for the operational performance of the CSPD. The machine capacity is of great importance due to fact that this is the rigid capacity of the department. The processes in most CSPDs are greatly dependent on the human resources. The work-design and work ethic of the CSPD staff can also have huge effect on the experienced capacity of the CSPD, though reorganizing and standardizing their task are operational concerns that can be adjusted along the way.

II.II Size and capacity requirements for storage

Keeping inventory is a measure taken to facilitate the smoothing of supply and demand and achieve satisfactory levels of customer service, when faced with uncertainty in demand. The only way to make sure that the hospitals are able to deal with unplanned use of equipment it to keep safety stock. (van de Klundert et al., 2008) The demand the primary activities of the hospital are facing is described as unpredictable by nature. The demand experienced in the CSPD will be directly influenced by the unpredictability, and additionally the processing times are relatively long. This underlines the need to keep sterile goods in storage.

Figuring out what and how much to keep in storage is however a complex task, that will impact the size and capacity required for storage. (Ahmadi et al., 2018) explains how the inventory levels will depend on the frequency and scheduling of the different procedures in the hospital. (McDonnell & Sheard, 2012) discusses how larger inventories will require larger storage area and higher cost but reduces the risk of running out of stock and emergency situations will be easier to deal with. The storage capacity in the hospital is often explained as limited (Birk, 2007; McFaddin & Earnhardt, 1999).

The sterile storage of the CSPD will be influenced by the service design of the CSPD, it's replenishment policies, the space requirements provided in Table 5 and the total storage configuration of the hospitals, which often is arranged as a multi-echelon inventory system (Volland et al., 2017). As explained in chapter 3.2.4 there can be multiple levels of storage in the sterile logistics loop. The hospitals often have centralized storages of reusable equipment in connection to the CSPD and decentralized storages close to the point-of-use in the departments (McDonnell & Sheard, 2012; van de Klundert et al., 2008). The CSPD storage capacity will be influenced by the total storage capacity of the hospital, and the decisions on what to store where.

At St. Olav the initial plan was for the CSPD to have a centralized storage with of sterile reusables. The CSPD would also have liked to process to a central storage and where equipment could be drawn directly from storage when needed. This would have allowed for a more stable flow in the CSPD. The storage configuration of sterile goods the hospital could have consisted in only a decentralized acute storage, and the rest of the equipment could have been kept in the centralized storage, in order to share resources and get a better overview on the accumulated inventory status. However, the limiting factor to this being carried out was the departments reluctancy to buy more equipment than they believed was necessary, due to tight budgets. As a

result, there was not enough equipment to maintain a central storage, and the equipment is now stored decentralized in the different departments. The shelves down in the sterile storage are left quite empty, except for some infrequently used specialized orthopaedic trays, and some extra trays for eye surgery. Otherwise, the storage mainly holds the clean carts, and equipment and material needed for the processing. During peak periods the storage is quite packed with carts waiting to be distributed. The hospital has chosen not to have the sterile single use equipment stored here; this is sent directly from the central warehouse at Heimdal to the departments' decentralized storages.

In the current hospital in Stavanger, single-use and reusable sterile items are mainly kept in the decentralized storages of the departments. Little is kept in the storage at the CSPD, which is mainly used for distribution and storage of equipment waiting to be distributed. But for their new CSPD, Stavanger has chosen another strategy for storage and distribution zone. The new CSPD will have a different service design where it will be responsible for the entire sterile supply in the hospital, both reusables and consumables. The purpose is to deliver 100% complete procedure carts from the CSPD to the surgery department. This will also include some equipment that is only disinfected and cleaned in the decontamination area, such as the equipment of the anaesthesiologist. This means that the sterile storage and distribution area must be dimensioned to fit both single-use sterile items, the reusable equipment, the clean equipment, the required cart and space for packing them. This will add on to the required storage capacity of CSPD, in contrast to the former solution. But will free up space in the surgery department, and save time seeing as the CSPD deliver the entire required output of the customer in one step, rather than requiring several steps at different storage locations to retrieve the different equipment necessary.

In order to incorporate the consumable sterile goods into the CSPD's storage, there has been decided to use an automated elevator dispenser storage, which utilizes not only the area, but also the volume. The price per square meter in the new hospital is so high that there will not be budget to provide any excess in area or high levels of buffer-equipment in storage. However, there will always be necessary to have some buffer of equipment, to make sure that the whole system is not set off balance in cases where a surgery takes longer than expected, and it is planned to use the same equipment in the following surgery some hours later. But the question is how large this buffer really needs to be. With smooth flow of equipment, continuous opening hours and sufficient staffing available at the right times, there is a belief that large buffer storages may not be required. On the other hand, as new medical procedures are introduced, the

older procedures are not phased out immediately either. So, the medical advancement will contribute to increased storage requirements.

III. Layout – What type of layout is required in the CSPD?

Layout can be referred to as the strategic resource organization of a facility. It is concerned with the relative arrangement of the transforming resources, which decides how the processed goods flow through an operation (Stevenson, 2014). This comprises decisions on the placement of different departments, work centres, machines, equipment and staff of the operation(Slack, 2013). In general, a layout should be designed to be safe, minimize flow length and production time, eliminate unnecessary movement, avoid bottlenecks, provide a clearly defined flow, utilize the space and workers in a good way and allow for long-term flexibility (Slack, 2013; Stevenson, 2014).

When arranging the layout of the CSPD, careful attention must be provided to facilitate for a clear unidirectional workflow from dirty to clean, that keeps clean and sterile supplies separate from contamination (Basu et al., 2014; WHO, 2016). To avoid cross contamination the processes are physically split into three separate departments; a sterile area, a clean area and a soiled area (Kobus, 2008). (McDonnell & Sheard, 2012) explains how serious consideration should be given to the designing appropriate layout and workflow in the CSPD, seeing as it is too often the case that the departments areas are found to be inadequate. In order to reduce error and increase efficiency the sterile processing workflow should be automated wherever it is reasonable, and be designed to eliminate redundancy and process variability (Johnson, 2005).The layout design of the CSPD is highly strategical, and organizational changes are rarely carried out unless there is a clear knowing that it will improve the processes. Simulation has therefore shown to be an effective tool to investigate how changing the organizational aspects of the CSPD impacts the processes, before making these decisions (Di Mascolo & Gouin, 2013; Lin et al., 2008).

At St. Olav the layout of the CSPD is separated into the three zones. The workflow is unidirectional from soiled to clean to sterile. The workflow through the departments have a U-shaped form due to the relative placement of the departments, and the dispatch and arrival areas of the reusable goods, which are placed in the same hallway. The flow of the CSPD is not explained as a levelled flow, mainly due to machine capacity and space restrictions. Without queues or complications, the flow from soiled to sterile takes approximately 4h for a regular tray of equipment. But the waiting times as normally 24h or 14h due to the accumulated demand

put on the CSPD. It is therefore operating far from a just-in-time mindset. The workflow is affected by some automation, when it comes to loading and unloading the equipment in and out of the washers and autoclaves.

The current layout of SPD at Stavanger Hospital in Våland consists mainly in the clean and sterile zone, while the decontamination is handled either in the decontamination zone of the surgery department or in the individual clinics. If the equipment arriving in the SPD is not found satisfactory clean, there are however two washers and a sink for rewash. The assembly and packing area is connected to the arrival area through a small corridor, which is filled with equipment waiting to be sorted and packed. The workstations are flexible when it comes to processing the equipment of the different surgical disciplines. The autoclave-sterilizers are put through the wall but the low-temperature plasma sterilizers (Sterrads) are placed in the sterile storage department. This means that clean, but un-sterile equipment is carried into the sterile storage area and for sterilization, which is not optimal. The layout at the current SPD in Stavanger is not 100% unidirectional from dirty to clean. It also has a U-shaped form, because most of the equipment is delivered from the surgery department by clean and soiled elevators, located on the same side of the SPD.

The layout for the new CSPD, is still a work-in-progress, but it is decided that it will have an U-shape. The functional architect explains how a straight-line layout would provide a clearer flow from dirty to clean. However, she explains that the starting point for the entire layout of the CSPD is to localize where the clean and soiled elevators are to be placed. Based on the location of these, the rest of the flow can be determined. The placement of the elevators is already fixed, as a part of the global design of the hospital. Their placement is tightly knit to the layout of the surgery department. Consequently, both the clean and soiled elevator must be in the same hallway, and the layout of the CSPD must have a U-shape.

The current preliminary layout of the CSPD has been sentenced as unfit by several stakeholders. There should be a logical flow of both equipment and people, that doesn't interrupt the unidirectional flow from dirty to sterile, and enough space to provide a good workflow without bottlenecks. As it is now, the layout does not facilitate a 100% unidirectional flow, and there is uncertainty on whether the space provided is enough. The layout is however of great importance for the operation performance of the CSPD and should be done right now that an opportunity has presented itself. The project group of SUS2023 are therefore in the process of providing a more satisfying layout design.

IV. Environmental conditions – How should the design facilitate for the required environment?

Construction of a CSPD presents some unique challenges in terms of the many environmental requirements that must be fulfilled in order to provide the right conditions for high quality sterile processing and storage (Chobin, 2001). The strict environmental conditions add on a layer of complexity to the process of planning the process design of the CSPD.

The main environmental and ergonomic considerations are summed up in Table 6. There are in example special concerns related to the choice of surfaces and interior such as workbenches, drains and sinks. There are also requirements to the environment in terms of light, noise, water quality, the temperature and humidity of the air in the departments. In order to avoid air-contamination the airflow also needs to be unidirectional and a certain air exchange rate is required. Both storage and transportation can also compromise the sterility. Necessary measures and environmental control must be provided to maintain the sterility of the equipment until use in immediate or future patient procedures. Best practice for maintaining sterility of the equipment is to minimize handling, and to store and transport correctly (McDonnell & Sheard, 2012).

In Stavanger, the old sterile processing department is characterized by the fact that it was designed to maintain the environmental requirements that was present in the 80s. It does not live up to the standards expected of a moderns CSPDs today. It does in example not have ventilation to facilitate for airflow from clean towards dirty, and the carts are not regularly washed. The new CSPD will however be up-to date and provide the environmental conditions required in a modern sterilization facility. In the layout there is planned to have a separate room for unloading the autoclaves as well, which prevents temperature and humidity changes in the sterile storage. The CSPD at St. Olav is constructed to uphold the environmental requirements of modern CSPDs. They do however unload the autoclaves in the same room as the sterile storage but compensates with extra ventilation in the ceiling above the unloading area.

Operational design decisions CSPD:

V. Service design – What services should the CSPD deliver?

The service design of the CSPD is an important decision, seeing as the service design decides what services the CSPD delivers, to whom and how. The service must be designed so that it can actually be implemented and to best possible provide the services required by its customers. (Slack, 2013) Hospitals are not-for profit organizations, so the main objective with the service designs are not to earn profit. However the serviceability of the CSPD is important, since this is connected to the services' ability to provide the services at an acceptable cost. (Stevenson, 2014) A general service goal of the CSPD is explained to be the deliverance of " 100% clean and sterile instruments, 100% complete instrument trays, delivered to the O.R 100% on time" (Johnson, 2005). Additional objectives and the details on how this is facilitated for will depend on the individual CSPD and their customers' requirements.

The services delivered by the CSPD at St. Olav delivers to its customer departments, are both procedure specific carts and single trays or equipment. But today the CSPD does in example not offer processing of the flexible endoscopes, this is still handled by the hospital department, but may be included as a part of the service design of the CSPD in the future. The services also come with a certain lead time of 24h or 14 h between the departments orders a service, until it is delivered.

At Stavanger hospital it has been a troublesome process to define what the service design of the new CSPD is going to be. This has led to an iterative and turbulent planning process. As of now, the service concept of the CSPD is leaning towards being a total sterile supply function. That will deliver complete procedure specific trays, with both the sterile reusables and single-use items, and most likely also the non-critical clean equipment required for the procedure. In addition to deliverance of single equipment and trays. This will have indications for both the capacity and job-design of the CSPD.

Service design is placed under the operational design decisions because the decision is related to the entire operational nature of the CSPD and its services. However, it could be argued that this decision also is highly strategical, seeing as it is an important prerequisite to know the service design to be able to design a CSPD that facilitates for these services.

VI. Technology – What technology is required in the CSPD?

Implementing the appropriate technology into the processes can have huge benefits and immensely improve an operations performance, however it is important to know the capabilities of the technology. New technology can be demanding to implement and integrate to the workflow. It will require training of the staff and reorganization of their tasks (Slack, 2013). As explained in Chapter 3.2.5.6 there are three types of processing technology, categorized based on what they process; materials, information or customers (Slack, 2013). The processes of the CSPD are highly dependent on both material and information processing technology.

Essential operations are performed by material processing technology, such as the washing and sterilizing machines. An important discussion concerning the material processing technology of the CSPD is to what degree it is purposeful to automate some of the processes. When it comes to information processing technology there are several information streams to manage in the CSPD. The quality of the processing is dependent on technology to continuously monitor the state of the machines and ensure their functionality. There is a need to manage inventory, and to track the flow of goods inside and outside of the CSPD. Using tracking and tracing systems the CSPD can collect and report activity and productivity data, keep records of the executed processing activities, and the position of the equipment. Such systems should be well incorporated into the workflow, so that the technicians don't have to stop their work unnecessarily in order to record the different events. The system should employ user friendly devices such as touch screen technology, bar-codes, RFID and automated or handheld scanners to collect data (Ahmadi et al., 2018; Bailey, 2001). The aim of the tracking systems is to ensure efficient and accurate flow of equipment between the CSPD and the point-of-care. It has shown effects such as reduced instrument loss, increased employee productivity, reduction of delays in delivery and downtime in the OR (Ahmadi et al., 2018; McDonnell & Sheard, 2012). Most hospitals also use some information systems to keep track of the planned surgeries and procedures. It is however quite common that the activities at the CSPD is not integrated in these systems, but is executed and planned independently (van de Klundert et al., 2008).

Both case hospitals utilize the same kind of information technology. To document the sterilization processes and track the goods through its logistics loops, the specialized Sterile management system T-doc is used. It does not provide real-time tracking, but the equipment is scanned into different locations using barcode and handheld scanners. None of the hospitals apply the integrated function for operation scheduling in T-Doc. Both hospitals use

"homemade" systems for operation scheduling and to keep track of what equipment to order. The orders are usually sent by mail or phone. To keep track of the inventory of consumable sterile goods both hospitals also employ an SAP solution.

The processing at St. Olav have automated loading and unloading of the equipment into the washers and sterilizers. In order to free the staff from heavy lifting. This is performed manually in Stavanger, but for the new CSPD they are still deciding upon what is a reasonable amount of automation with the new processing volumes. The new CSPD in Stavanger will most likely continue to use the familiar T-doc system. The CSPD manager would like to integrate operation scheduling and the tracking systems in the new CSPD. It would be of great advantage if the required instruments were automatically booked once the operation was scheduled. Additionally, a technology driven priority system could make it easier to see what must be processed next. Preferably a screen that provides real-time queuing of the waiting equipment, based on operation schedules, and in case of rush orders this could be alerted and moved to the top of the queue. This would however require real-time tracking. A goal with the new CSPD is also to make better use of the information gathered by the IT-systems, to recognize behavioural patterns and enable the CSPD to plan for how to best meet the demands. The more information, the better ground for making managerial decision and discovering potential for improvement.

The technology decision is also in the grey zone between operational and strategical. It is placed under the operational design decisions because the decision is related to the operational nature of the CSPD and its workflow. However, the choice of technology to support the processes can also be considered as a strategical decision, though not as fixed as location or capacity.

VII. People, jobs and organization – What are the required human resources and how should they be organized?

Managing human resources entails deciding upon the required skills and allocating the different tasks of a process. The job design is important, both for the employees but also for the productivity and quality of the work performed. The job-design can involve individual- or teamwork, a high degree of standardization and division of tasks, or job-rotation. There is also a physiological aspect to the job design, which is involved with providing ergonomic workplace designs (Slack, 2013).

In the CSPD, skilled and dedicated staff are often considered the most valuable resource of every reprocessing area. (McDonnell & Sheard, 2012) The processes of the CSPD are knowledge- and labour-intensive, at times very busy and relies heavily on its employees. Investing in the skills and training of the staff is just as important as the physical resources of the CSPD. (Basu et al., 2014) The employees of the CSPD must be able to operate the system efficiently, know the importance of infection control and understand their role in the process. Capacity problems in a CSPD is not necessarily directed to the machine capacity in the department. The job-design and employees are also important prerequisites for making the best out of the machine capacity available.

At both St. Olav and Stavanger Hospital the employees rotate between the departments and tasks. This provides a flexible work-capacity, reduces monotony of tasks and increase the skill-flexibility of the workers, who are keeping all the different tasks fresh in mind. It is also linked to HMS and ergonomic concerns, by rotating on the tasks that require heavy lifting. At St. Olav the CSPD is operated 24h in weekdays. The SPD in Stavanger is not open during night-time, but with the new CSPD the operating times will be expanded to 24h there as well. This allows for more processing flexibility, around the clock.

The biggest time thief is explained by the logistics manager in SUS2023 as when staff are put to do tasks that are not within their field of expertise, such as a logistics or cleaning task. This will impact the productivity of their shifts. They have experienced success with dedicating tasks that are typically secondary tasks of the CSPD staff, to other working groups, that can incorporate the tasks as one of their primary functions instead. In this way, the tasks are usually performed better and with more willingness. The jobs-design will also be influenced by implementing new equipment to be processed or to be used in the processing. Adaption will be required if faced with new technology, both in the form of new IT-systems and automation. Some tasks will disappear, and new ones will appear. At St. Olav there is also a wish to hire more technicians who are specialized in sterile technique and finding the correlation between the daily processing needs and the required number of employees.

Summary of the Design Decisions

A table is used to sum up the main design decisions and with additional explanatory sub-decisions.

Table 9: Summary of Strategical & Operational design decisions - Findings

STRATEGICAL DESIGN DECISIONS
I. Where should the CSPD be located?
- *How should it be placed relative to the main distribution flows and main customer departments?* - *What transportation solution should facilitate for the distribution between the CSPD and its customers?* - *Could a closed sterile loop be facilitated between the CSPD and surgery?*
II. What are the long-term capacity requirements?
II.I. What is the required size & capacity of the processing departments?
- *What functions are facilitated by the sterile processing* - *What is the required machine capacity to match the long-term demand?* - *How much space is necessary to room the required machines, equipment, materials, workstations, staff and facilitate for a good workflow?* - *How can long-term flexibility in capacity be included in the design?*
II.II. What is the required size & capacity of the sterile storage of the CSPD?
- *What is stored where in the hospital supply chain, and what material medical/sterile goods are to be stored in the CSPD storage?* - *What storage area is required for additional storage of carts?* - *What storage solutions will be utilized in storage?* - *What area and volume are required to room all equipment in their storage solutions?*
III. What are the layout requirements in the CSPD?
- *How to facilitate a unidirectional flow of goods and personnel that hinders cross-contamination?* - *How should the transforming resources be arranged relative to each other to facilitate a good workflow?* - *What degree of automation and standardization should be incorporated into the layout?*
IV. How should the design facilitate for the required environment in the CSPD?

- *How to facilitate for the required airflow and circulation that eliminates cross-contamination and keeps required temperature and humidity?* - *What surfaces and interior should considerations should be taken?* - *How to avoid compromising the sterility of the sterile goods?*
OPERATIONAL DESIGN DECISIONS
V. Service Design – What services should the CSPD deliver?
- *Who will be the customers of the CSPD?* - *What services does to customers require of the CSPD?* - *How should these services be delivered?*
VI. Technology – What technology should be applied in the CSPD?
- *What material processing technology?* - *What information and communication technology should be employed?* - *What systems should process which information? Should there be an integration between IT-systems?*
VII. People, jobs & organization -What are the required human resources and how should they be organized?
- *What human resources and skills are required?* - *How should the employees be organized?* - *How should the job design be?*

RQ2: How can a systematic design procedure facilitate for CSPD designs that meet the future requirements?

Based on indications from the literature, the Empirical findings and input from Sykehusbygg HF, there is a lack of a systematic procedure for designing the Central Sterile Processing Departments as of today. It's appears the design process and the timing of the different steps involved, vary from project to project, with additional variations in the degree of success in the end results.

In literature it is explained how the design and configuration of the CSPD will vary due to several factors that will depend both on the external factors such as the size and demography of the population the it serves (WHO, 2016), but also due to the internal factors such the size of the hospital, the number of beds relying on the departments' services, average surgery numbers and types, the operating hours of the SPD and the number of employees per shift. (WHO, 2016) It is stated by (McDonnell & Sheard, 2012) that a correctly designed CSPD is the first step towards ensuring patient safety, and that serious consideration should be given to designing an appropriate layout, seeing as it is too often the case that the departments areas are found to be inadequate.

A large share of the literature is concerned with seeking improvements of the operations at the CSPD, such as optimizing the sterilization logistics (van de Klundert et al., 2008), the sterile processing workflow (Johnson, 2005) the inventory levels (Ahmadi et al., 2018) or the bottlenecks present at the CSPD (Ozturk et al., 2014). (Dziwis, 2010) explain the Central Sterile Processing Department (CSPD) often struggles with capacity issues, like many areas of the hospital. And (Swenson, 2013b) explains how there are needs for increasing the workforces, renovating and reorganizing many CSPDs, or in some cases provide an entirely new department. (Chobin, 2001) emphasises how the opportunity for building new or renovating the existing CSPD does not present itself often. When it does it is therefore important to plan a sterile department that will be able to meet the needs today and at least couple of decades ahead in time.

There is also literature on how simulation can be used as a tool for designing and predicting the impact of making organizational changes to the design and workflow at the CSPD. (Lin et al., 2008) investigate how simulation can facilitate the design of a central sterilization department. They utilize simulation to analyse department configuration, equipment capacity, staff

schedules and cart-wash requirements. The results are analysed based on performance measures such as tray turnaround time, the rate of delayed surgeries and levels of WIP. (Di Mascolo & Gouin, 2013) also applies simulation to assess the performance of sterile services. They explain how CSPD services are highly strategical and organizational changes are rarely employed without knowing in advance that it will result in improvements. That's why simulation is a handy tool in the design process. In the general theory on process design, chapter 3.1.6 includes an explanation of the Systematic layout planning procedure (SLP-procedure) provided by (Muther, 1973). The SLP-procedure is a step-by-step planning procedure, describes as "a universal approach for systematic layout planning." The procedure is mostly directed towards industry, but also highly relevant in the CSPD setting. It incorporates many of the design decisions that is relevant for design of the CSPD.

To sum it up, there are strong indications from literature that there are experiences with inadequate sterile services and that there is an interest in the field for improving the performance and the design of the CSPD. Simulation has been used in the process of figuring out the best configuration and design of the sterile department. But nowhere have there been suggestions on how a more systematic design procedure could help facilitate for design that is better suited for meeting the future requirements. Therefore, this study will contribute to filling this research gap.

Empirical Findings

When investigating the design procedure of a CSPD the input from the case study at Stavanger University Hospital is highly relevant. The case provides insight to a real-life design process and its complexity. An immense number of different actors are involved in the process of finalizing the design of an CSPD. The hospital management, the service providers of the CSPD, the service receivers, specialists in the field of infection prevention and control, project planners, engineers and architects are the actors identified in this thesis. With many stakeholders, there are also naturally conflicting interests involved. For the decision-makers it is important to have the right input, from the right actors, available at the right time, in order to make valid design decisions. Orchestrating this is a comprehensive but important task, which has shown to be a challenge in the planning process of the new design of the CSPD in SUS2023.

In chapter 4.1.3 the perspectives of four important participants of the CSPD project is provided. They share different insight into the design process, it's challenges and their expectations. One important issue that has made the design process more challenging than necessary is the fact

that there was no clear agreement from the start on the activities and functions of the new CSPD. What started out as a "basic" sterile processing department, has evolved into a complete sterile supply function serving as a complete washing function, sterile processing function and a storage for both clean equipment, sterile reusables and sterile consumables in 100% complete procedure carts to the surgery department. But many iterations where necessary before deciding on the service design of the CSPD. There are in example still uncertainty on whether the CSPD will take care of washing all non-critical devises, and whether this would require a dedicated washing line.

The fact that there has been confusion on what functions the CSPD will provide, have had consequences for planning process, and resulted in lot of extra work for the project group. It has resulted in analysis's and simulations being carried out with the wrong input, and designs being drawn on the wrong premises. Along the process it has been made more clear what the purposes of the CSPD will be, and the project are now starting at "ground zero" again, with gathering new input data, to provide new analysis, and a new design again. It has so far been a very iterative process, were several steps could have been avoided had a systematic designing procedure been applied.

But once the functions and tasks of the CSPD are decided upon, several challenges remain. Another challenging task is to provide valid data input to base the long-term capacity calculations on. It has been challenging get a good idea on how the capacity requirements will be affected by the centralization of what today is quite fragmented activity. T-doc provides historical data on what has been processed in the SPD. However, all activities performed elsewhere in the hospital, such as equipment washed locally in the departments, does not have documented history. There are also implications from the case at St. Olav, that the long-term machine capacity and space requirements calculations were not sufficient. After 10 years the department is already working at maximum capacity, while the long-term capacity was forecasted for 20 years. The root-cause to what is experienced as capacity shortages at the CSPD at St. Olav does are however depend on several interlinked factors, not solely the capacity calculations. There seems to be a trade-off between spending money on either supplementing the reusable equipment in the departments or the machine capacity at the CSPD. But there is a clear agreement upon that space dedicated to the CSPD will not be sufficient in the future, with the way the CSPD operates today. When the CSPD was planned, a fixed area where dedicated to the CSPD early in the planning process. The management of the CSPD argue that a better solution would most likely have been provided if the department had been

designed from the inside out, to facilitate for the required quality and functionality of the department before physical restraints were given.

At Stavanger hospital the project group of SUS2023 share the same worry on whether the area dedicated to the CSPD is enough, seeing as it was not based on a clearly defined set of tasks and their capacity requirements. The price per square meter in the new hospital is so high that there will not be budget to provide any excess in area. The goal is rather to provide for efficient utilization of the area and volume provided. There are however discussions on whether the area that now is dedicated as personnel area, might be moved in order to free this space for the CSPD. If valid calculations on the capacity requirements were provided early in the process, based on an agreed upon set tasks, this would have been important input to influence the area provided for the CSPD. Which again would provide better adapted and more functional designs.

Yet another challenge is the fact that the CSPD must be well-integrated in the hospital. Placing the CSPD inside the hospital environment and relative to all the primary and secondary processes at the hospital does not simplify the design process. The CSPD needs to blend in as a natural part of the entire hospital. It cannot be sub-optimized at the expense of primary activities or other important supporting services. The global design of the hospital has important implications for the freedom to decide the location and design of the CSPD. Providing optimized CSPD would be an easier task, if freed from the hospital construction. This may be one of the reasons why the trends are moving in the direction where more and more patient-related and logistic priority fields, such as sterile logistics are being outsourced. (Kriegel et al., 2013)

There is no question that designing the CSPD and its processes is a complicated puzzle. A more systematic design procedure would have helped the design process of SUS2023. Having the right information available at the right time is a prerequisite for making good design decisions, avoid extra work and provide grounds for designing facilities that have best possible functionality now and in the future.

Suggestion of a systematic design procedure for CSPD process design

Developing a standardized design for the CSPD is close to impossible. Each CSPD have its individual differences and will be influenced by different external and internal factors and correlations. Despite the different influences, most of the identified design-decisions will be relevant for all CSPD designs. The required input information will be quite similar even though their "values" will vary. Therefore, inspired by the SLP procedure developed by (Muther, 1973) and with the valuable insight from the cases and literature, a systematic design procedure for the CSPD process design is suggested. The systematic design procedure is illustrated in Figure 30. The rest of the chapter is dedicated to describing and discussing the suggested systematic design procedure.

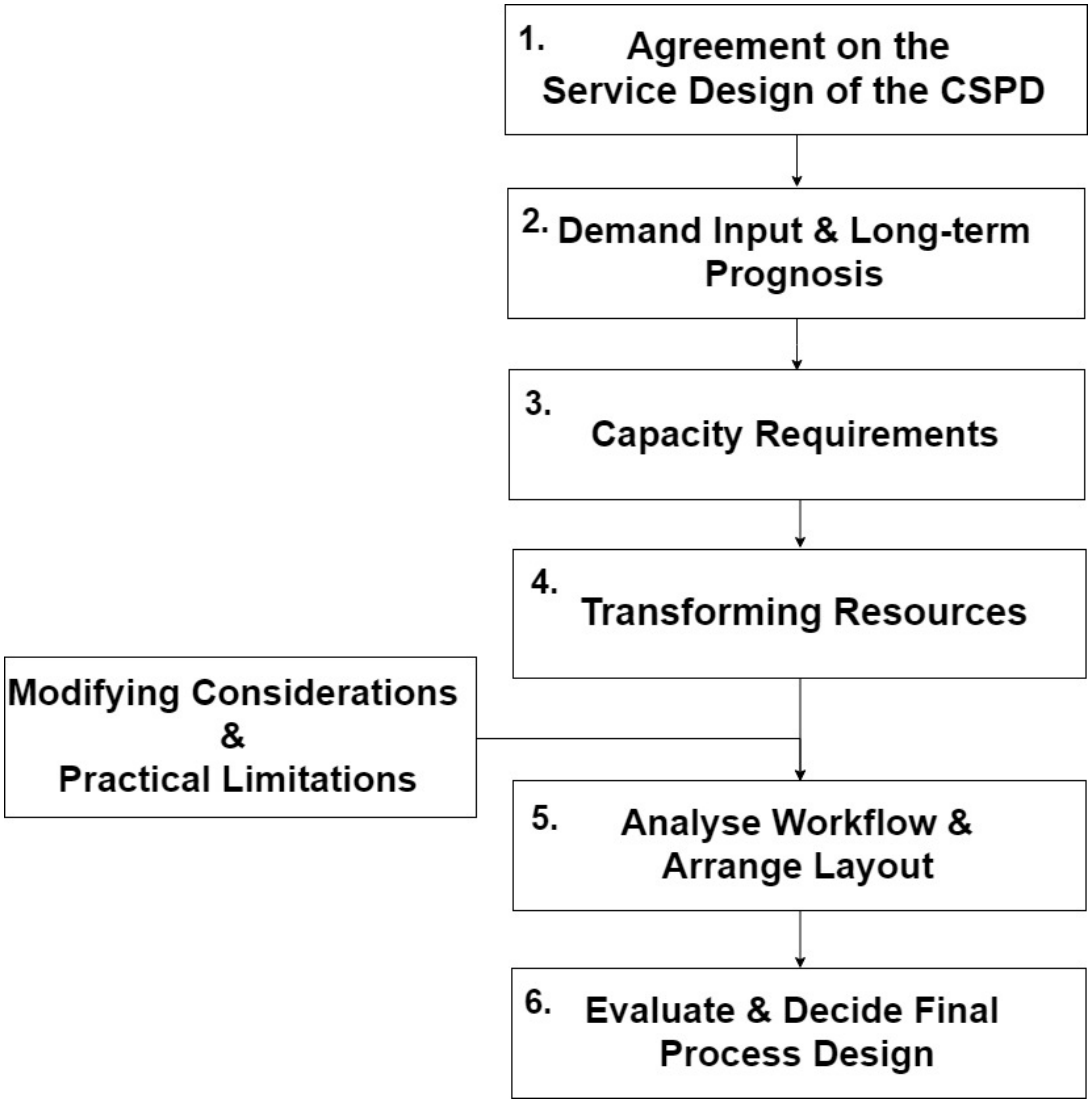

Figure 30: Suggested systematic design procedure for the process design of the CSPD

The six steps of the Systematic procedure

1. <u>An official agreement on the functions and activities of the CSPD</u>

It should be clearly stated who the customers departments of the CSPD are, and what functions and activities the CSPD are expected to carry out for the customers.

2. <u>Collect demand input & provide long-term demand forecast</u>

Based on the official agreement on functions and activities the CSPD will carry out, the related input data must be gathered from every customer department in order to the determine the total demand put on the CSPD, and how it is expected to change in the long-term future.

Important input:

Products/services	-	What is to be processed and or distributed?
Quantities/*Volume*	-	What is the processing volume and frequency of each product?
Process requirements	-	What are the processing requirements of each product?
Processing Sequence	-	What is the processing sequence/route the different products?
Demand forecast	-	Long-term demand: How are products, quantities and processing requirements expected to change in the future?

The output will be the mix and volume that needs processing, and its processing requirements. An analysis tool should be used in the process of creating the forecast, and all known factors on trends and future development that will impact the demands should be included.

3. <u>Translate the demand input into capacity requirements</u>

Processing machines Capacity	-	How much processing capacity is required of each type processing machine?
Processing time/cycle	-	What are the processing times of the machines per cycle? *this will depend on the choice of machines
Manual labour capacity	-	How much capacity is required for the manual labour tasks?
Manual labour time per batch	-	What is the average processing time of the manual labour processes per batch? *will depend on job-design & available staff
Inventory capacity	-	What is the required inventory capacity to match the processing capacity? *will depend on the quantity of reusable equipment in rotation

The output will be in hours per period of time (e.g.day) per processing activity.

Input on alternatives of processing times per cycle of the machines must be given from the suppliers of the processing machines.

4. Translate the capacity requirements into transforming resources

With the opening hours of the CSPD as input, the processing hours, per period time period, per activity must be translated into transforming resource capacity required to get the work done within given time frames. Using in example the hour with most workload as dimensioning factor.

Relevant transforming resources:

- Washingmachines for reusable equipment
- Cart Washers
- Sterilizing machines
- Workstations in all three zones
- Carts
- Staff
- Transportation means

Translating the capacity requirements into machine and equipment requirement be done in collaboration with suppliers of the machines/equipment who knows the cycle times, capacities and characteristics of the different equipment.

5. Analyse workflow and arrange layout

Once the quantity of the different transforming resources is decided upon, the next task is to arrange the resources in a layout that facilitates for a process that performs accordingly to the objectives it seeks to achieve. In order to do so the objectives of the layout and the related performance measurements to these. Analyses are carried out e.g. using simulation. Simulation has proven to be an effective tool to investigate how changing the organizational aspects of the CSPD impacts the processes, before making final decisions. (Lin et al., 2008) (Di Mascolo & Gouin, 2013)

The routes of the different materials will be important input. The main flows and processing sequences should be identified and taken into consideration when arranging the transforming resources. Another important input will be the space requirements of the different transforming

resources, including the space needed to operate it, and for movement of staff and carts. Alternative configurations of the three zones in relation to each other, as well as the internal arrangement of the main transforming resources can be developed. There will however be several practical limitations and modifying considerations involved that must be included in order to provide valid designs. The required modifications will depend on the individual CSPD.

Important modifying considerations & practical limitations can be:

- The physical separation into three zones
- The unidirectional flow of goods from soiled to sterile
- If the area of the CSPD is set before the planners have reached this point of the planning, the space dedicated to the department will be an important modifying consideration.
- Location
- Job design and workflow of the employees
- Supporting technology
- Environmental concerns
- Transportation concerns
- Budgets

6. <u>Evaluate and decide final design</u>

The different designs and layouts should be evaluated. For this purpose, the performance measures decided in step 5 can be utilized. Benchmarking, including the important stakeholders and exchanging experiences with departments of similar demand and capacity characteristics can be important input evaluate and make final adjustments before the final design is decided upon.

Discussion

The contingency theory as explained in Chapter 3.1.6 is highly relevant in a hospital setting, seeing as the hospitals are subject to many internal, interdependent and external factors that will impact it's decision making.(Hayes, 1977) It states that there is no best way to make decisions in an organization. To a degree this applies to the design decisions related to the process design of the CSPD. The decisions will be influenced by external factors that are out of the control of the planners. The external factors will complicate the task of providing valid long-term demand forecast to base the designs on. Several internal factors will influence the required process design as well. Such as the characteristics, amount and frequency of medical procedures in the hospital, the inventory levels sterile goods, the services the departments require of the CSPD. The external and internal factors of influence will vary for the individual CSPD, and due to these one may argue that it is no best way to make the design decisions of CSPD.

Providing a detailed and overall systematic design procedure that will be applicable to every CSPD project proved challenging. Therefore, the systematic design procedure does not in detail include all the design decisions identified in RQ1. The level of detail has been reduced to the basic steps that will be relevant for every CSPD project. There will always be of importance to agree upon the service design early on in every design process, seeing as this is a prerequisite for designing CSPDs fit for providing the services required. The demands experienced by the different CSPD will vary, but for every CSPD there will be need collect input on the demand, factors that influence the demand and providing a long-term demand forecast. Translating the demands into capacity requirements and the required transforming resources will also be necessary. There should also be conducted analysis of workflow and simulations of different layout arrangement in order to provide a layout that is best fit to reach the objectives of the process. And finally, these solutions should be evaluated, and a final design provided as output.

Some of the input factors included in the description of the design procedure might be hard to predict. In example providing predictable processing times on the tasks that involves manual labour can be challenging. However, the more standardized the job-design and the more tasks left to automation, the easier it will be to predict the process durations.

The analysis flow, arranging the of layout, figuring out the total space requirements and evaluating it, will most likely be an iterative process. The modifying considerations and practical limitations are included as input to this step. These considerations and limitations will represent several individual differences and considerations such as splitting the physical

separation of the three zones, facilitating for a unidirectional flow and the required environmental conditions. If there is placed a physical restriction on the area already, this would also be a practical limitation. The nature of the analysis would then be changed into finding the best way layout and flow within the space dedicated. However, the overall thought is that the space restrictions are not to be placed until the capacity and space requirements are calculated. This would require the hospital planners to carry out step 1-5 in the early phases of the project, which may not be realistic for every CSPD project. As seen both in the SUS2023 project and at St. Olav, the global design of the hospital was decisive for the area dedicated to the CSPD. But as the architect of SUS2023 emphasises; if early capacity and space calculations were carried out before the global design of the hospital was fixed, this would have been important input to deciding the dimensions of the CSPD.

Design decisions such as what technology should be applied, the location the CSPD and the job-design of the it's employees can also be important to include in the procedure, but the timing of when these decisions are taken can be hugely variating. The job design might be a part of the strategical objectives of the CSPD which the layout will need to adapt to, or the job design might follow as a consequence of how the layout was arranged. The exact location might be decided before the project of designing the CSPD is even initiated and be of importance for how the service design is constructed. It may also come with certain modification such as the placement of clean and soiled elevators, as experiences in the SUS2023 project. These individual considerations and limitations will need to be included in the systematic procedure as best fit. Another aspect that must be included in every design procedure are economical limitations. Due to budgets, the possibilities are not endless. As explained by the logistics manager of SUS2023, the price per square meter in a hospital is high. Technology and automation are also among the decisions that require high initial investments. There will always be of interest to provide satisfactory CSPD designs but keep the costs as low as possible.

Therefore, the systematic design procedure presented is not a complete representation of all the processes and design decisions involved with designing the CSPD, with all it's complexities and individual dependencies. It does however include the processes that are highly relevant for all CSPD, while the individual differences are accounted for through the modifying considerations & practical limitations. A weakness of the design procedure is also that the result will be highly dependant on the analyses, whose details are left out of the scope of this thesis. The designs' ability to meet the future requirements will be highly dependent on factors, such as the precision of the long-term demand forecast and how much flexibility there is possible to

include into the design. But the systematic design procedure is a great starting point for further development of decisions tools for the hospital planners. It would provide the actors involved in the project with a unified and systematic order on what information should be gathered before certain steps are carried out. The objectives and functions of the design would be agreed upon early, and unnecessary work could be ruled out.

6. Conclusion

The conclusion summarises the findings of the thesis and provides the concluding reflections on how the research questions were answered throughout the thesis. The thesis' contribution to theory and practice will be elaborated on, before the limitations of the thesis and interesting indications for further research in the field will be presented.

This thesis has investigated what the important design decision related to planning the CSPD are. It has explored how applying a systematic design procedure can help the hospital planners make valid design decisions and provide CSPD designs fit to meet the future requirements. The overall research goal has been to facilitate for planning the process design of the CSPD from the inside and out, so that the functionality of the sterile departments can be made a priority when strategic decisions are being made.

Research question 1 aimed at identifying what the important design decisions are when designing the processes of a Central Sterile Processing Department. Based on the findings from the cases and justification found in literature, a set of important strategical and operational design decisions where identified. The long-term strategical decisions related to the process design of the CSPD are concerned with its location, the long-term capacity and size requirements, the layout and the environmental requirements. The operational decisions are related to the choice of service design, the technology to apply and how the employees are organized, and their jobs designed. The strategic and operational decisions have shown to be somewhat overlapping, the strategical decisions have important implications for the operational performance of the CSPD, and vice versa. An important prerequisite for making the correct strategical decisions is to know the objectives the operational service seeks to achieve.

Research question 2 aimed at investigating how a more systematic design procedure can facilitate for CSPD designs that meet the future requirements. Based on indications from the literature and important input from the case studies and Sykehusbygg HF, there is a lack of a systematic approach to designing the CSPD. The process of planning a CSPD has been

identified as a complex task that require the involvement of several actors. It can also be characterized by having several stakeholders with conflicts of interests. Nonetheless, the design decisions involved are influenced by both external and internal factors, as well as several interdependencies within the hospital. The lack of a systematic design procedure has further complicated the design process for the project group of SUS2023. Having the right input available at the right time has proven to be a necessity in order to provide satisfactory CSPD designs. Facilitating for this could have saved the project group of SUS2023 from duplicating the design processes. If the design decisions are made on wrongful assumptions, the final designs will not be fit to meet all the future requirements. This will be reflected in the processes and their ability to perform, now and for the next decades. A systematic design procedure can help facilitate for a more unified design process for all involved.

The answer of the research question resulted in a six-step suggestion to a systematic design procedure for the CSPD process design. The design procedure includes the main steps that will be required in every design process resulting in a well-functioning CSPD. While the considerations to be taken due to the individual internal, external and interrelating factors of influence are included as modifying considerations & practical limitations. The first step consists in providing an official agreement on the service design of the CSPD. Knowing the service that the CSPD is expected to deliver is crucial for providing designs that achieves exactly this. In the second step the required demand input must be collected, and a long-term forecast conducted. This will serve as input to identifying the long-term capacity requirements of the CSPD, which is step three. Step four translates the capacity requirements into the required transforming resources. In step 5 the workflow is analysed, and the transforming resources arranged into layout suggestions. Included in this step is input on important modifying considerations and practical limitations that will influence the individual design. The final step consists in evaluating different layout, and deciding upon the final process design. As decision support it will be important to include important stakeholders, exchange experiences with similar CSPDs, benchmark and conduct simulations.

There is reason to believe that following such a systematic procedure would at provide the best prerequisites for providing CSPD process designs that meets the future requirements. How well suited the designs will be to meet the future requirements are also highly dependent on the quality of the analyses', forecasts and the input provided. However, the systematic design procedure is a step in the right direction towards providing the hospital planners with the decision support required in this complex process.

The study adds to the research on sterile processing design and sterile logistics. It provides an overview on literature and research related to process design, as well as two complementary case studies. To the authors knowledge there exists no research dedicated to identifying the important design decisions in the process design of the CSPD nor on developing a systematic design procedure for its purpose. Therefore, the thesis will contribute to filling this research gap. Seeing as there is no systematic design procedure being applied in practise, the thesis is a contribution to filling the practical gap also. The thesis will hopefully have implications for the practise of designing sterile departments from the inside and out, in the sense that the systematic design procedure can be further developed into a tool for decision support.

Limitations

There are some limitations related to the research conducted in this thesis, both with regards to the literature study and the case-studies conducted. A limitation related to the literature study is the fact that there is not much scientific literature available on the topic of process design of the CSPD. Similar studies could have provided better grounds for generalizing the findings. Some of the literature included are studies provided by practitioners in the field of sterile processing. These practitioners might be bias have preconceived notions based on their individual experience on the field, which takes away from the generality of their studies. There also exist an immense amount of different terminology for the sterilization practice and the processes at the CSPD. This could lead to confusion or undiscovered literature on the field.

Limitations of the case studies is first and foremost the fact that only two case studies were conducted. This gives an indication of the situation, but it will not be completely representative for the practise in general. This leaves little room for generalizing and drawing conclusions of cause-effect considerations. Finding appropriate case studies was a challenge seeing as there is not a frequent occurrence to find hospitals involved with the exact process of planning a CSPD. The empirical data collection can be coloured by the researcher's assumptions and the general opinion of the practitioners in the field. Simply by being present, the researcher might influence what is being said, done and may change how things unfold. The case studies have been conducted in Norwegian. Some of the meaning might have gotten distorted in the translation from Norwegian to English in the thesis. There is also quite a lot of internal "hospital slang" that could lead to confusion. The case studies are comprehensive, and a massive amount of data is collected in order to get to the core of the problem.

Further research

The thesis provides several possibilities for further research. It should be investigated how the systematic design procedure can be further developed into a decision support tool for the hospital planners. The generalizability of the systematic design procedure should be further explored. There are still many details to be figured out regarding what the analysis and simulations should incorporate. The process of providing valid long-term forecasts is an interesting field for further research. The same goes for the simulations included in analysing the workflow and arranging the layout.

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Elise Keseler

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NTNU
Norwegian University of
Science and Technology