Reducing the turnaround time in the histopathology service

- Experiences of an improvement process

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Sammanfattning

Stort fokus riktas idag på att kartlägga och reducera väntetider inom cancervården. För långa och variabla svarstider fördröjer behandlingsstart och väntan innebär dessutom psykiskt lidande. Syftet med förbättringsarbetet var att etablera en effektiv och stabil patologiprocess med kortare svarstider, utöka kundsamverkan samt bygga kunskap om interna processer för att lägga grunden till en lärmandemiljö. Målet var att senast den 31 december 2014 höja andelen besvarade vävnadsprover från 50 % till 90 % inom 15 dagar. Studien av förbättringsarbetet syftade till att identifiera faktorer som påverkar införandet av nya arbetssätt. Såväl kvantitativa som kvalitativa metoder användes för att uppnå målen; förbättringskunskap kombinerades med lean-inspirerade metoder och två fokusgrupper där data analyserades med kvalitativ innehållsanalys.

Målet att höja andelen vävnadsprover som besvarades inom 15 dagar på 90 % uppnåddes inte för samtliga provtyper, men tydligt förbättrade svarstider noterades. Kundsamverkan och visualisering av processerna hade en positiv effekt på personalen. Studien resulterade i sex viktiga faktorer; kompetens, inställning, återkoppling/feedback, interaktion, patient- och kundfokus och resurser. Motiverad och engagerad personal är nyckelframgångsfaktorer i förbättringsarbeten i motsats till resursbrist och människor som motsätter sig förändring. För att på sikt uppnå högt uppsatta mål krävs fortsatta förbättringsinitiativ som involverar optimering av både personalresurser och instrumentering.

Nyckelord: förbättringsarbete, svarstid, framgångsfaktorer, patologi, väntetid
Abstract

Today great efforts are made to record and reduce waiting times in cancer care. Long and variable turnaround times (TATs) delay the start of treatment and waiting contributes to mental anguish. The purposes of the QI intervention were to establish an effective and streamlined histopathology process with shorter TATs, to extend customer collaboration and to build knowledge of internal processes in order to lay the foundation for a learning environment. The goal was to raise the proportion of reported tissue samples from 50% to 90% within a 15 day period, ending 31st December 2014. The study of the QI intervention intended to identify factors that affect the introduction of novel working methods. Both quantitative and qualitative methods were used to achieve the goals. Improvement knowledge was combined with lean-inspired methods, and two focus groups were arranged in which data were analysed using qualitative content analysis.

The goal to report 90% of tissue samples within 15 days was not achieved for all sample types, but improved TATs were clearly noted. Customer collaboration and visualisation of the processes had a positive effect on staff. The study resulted in six key factors important working with QI interventions; competence, compliance, feedback, interaction, patient- and customer focus and resources. Having motivated and dedicated staff is a key success factor for improvement work, in contrast to a lack of resources, and people that oppose change. To achieve future ambitious goals requires continuous improvement initiatives that involve optimisation of both human resources and equipment.

Keywords: quality improvement, turnaround time, success factors, histopathology, patient waiting time
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Introduction

Cancer is a potentially mortal disease that affects millions of people worldwide. The increased morbidity and mortality rates are not only due to the aging and growing population, but also due to risk factors such as unhealthy lifestyle, high calorie food, and tobacco use (1). In 2008, an estimated 12.7 million people received a cancer diagnosis and about 7.6 million died of the disease worldwide (2, 3). These numbers are expected to increase, and by the year 2030 about 21.4 million new cases and 13.2 million deaths are predicted. A summary of 184 countries from 2008 shows that breast, lung, colorectal and prostate cancers account for about 50% of the total cancer burden in developed countries (2).

Cancer is the second most common cause of death after cardiovascular diseases in Sweden (4). In Scandinavia approximately 150 000 people are diagnosed with cancer annually and Sweden accounts for about 58 000 of these cases (5). This means that 1/3 of all residents in Sweden will suffer from cancer at some time during their lifetime. With an incidence of 1.7% in the last two decades, new data indicates that the cancer rate in Sweden is increasing and skin cancer shows the largest increase. Prostate cancer and breast cancer represent 1/3 of all cancers in Sweden, and skin cancer is the second most common cancer form followed by colon cancer. In a global perspective, Sweden has long been at the forefront of cancer care, research and prevention, which has led to good survival rates among cancer patients. This research must be preceded. Estimates from the Central Statistics Office in Sweden, show that in 2030, 317 000 people will have been diagnosed with cancer within the last five years, almost twice as many as today (5).

To guarantee that all Swedish citizens receive adequate health care within a specific time period, the law on guaranteed healthcare was passed in 2010 (6). This means that all citizens have an equal right to equal health care, and it has increased the pressure on the Swedish health care services to improve, monitor and reduce their turnaround times (TAT)\(^1\), both within and between caregivers. Also in 2010, the Swedish National Board of Health and Welfare was given the assignment by the Swedish government to map turnaround times in cancer care and also to suggest how they should be described and monitored in the future (7). The investigation showed that there was a lack of consensus on how the quality registries were used in terms of which waiting times were measured and which measuring point was registered. Furthermore, it was discovered that the quality registries mostly reflected the TATs of the organisation and did not indicate the patient waiting time. A report from 2013 further showed the difficulty of determining at what point in the clinical process the patients are informed about their diagnosis (8). The reason for this is that a cancer diagnosis is initially a suspicion that strengthens to a certainty over time. In reality, this means that the diagnosis based on tissue samples can be made at various stages throughout the clinical process, depending on which disease is suspected.

An important contributor to increasing the current state of comprehension and to identifying differences between regions and councils is the report “Quality and Efficiency in Swedish Health care – Regional comparison” (9). This report from 2011 contains medical results, patient experiences and waiting times. The report concludes that Swedish cancer care in general is of good quality, but varies in both availability and in medical outcomes. This means that there is room for improvement in terms of better cooperation both between and within counties, which would lead to reduced utilisation of resources. The report from 2011 covers

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\(^1\) Turnaround time (TAT): the amount of time it takes to fulfill a request
The six Regional Cancer Centres (RCCs) were formed in 2011 to improve Swedish cancer care (11). The RCC in the south-east region promises patients that treatment should begin within four weeks from the first visit to the doctor. Together, the six regions also handle and develop INCA², an information network containing 50 quality registers that manage records of cancer patients regarding health care and research. With new government funding, the aim is to further improve the accessibility and to reduce the patient waiting time (12). The SALAR has been responsible for supporting RCC in this important work. Among others, focus areas are how to reduce turnaround time in clinical histopathology and how to support the development of efficient processes (13). To obtain a more standardised process in Swedish health care, the Ministry of Social Care has started a project that is inspired by the Danish “pakkeforløb” (14, 15). The first part of the project will develop Patient Reported Experience Measures (PREM) questions to evaluate patient satisfaction with the care they receive. The project will also develop a standardised process for at least four cancer diagnoses. This means that each cancer diagnosis has its own timeline, with a maximum turnaround time between examinations and treatments. Other countries, as UK, has accepted this challenge and have used improvement knowledge to streamline their processes (16).

Improvement knowledge in health care

Improvement knowledge is a field of knowledge that includes theories, methods and tools about (micro)system, variation, leadership, change psychology and learning (17). Improvement knowledge in health care is about developing quality and implementing changes that result in better care and treatment for patients. This knowledge contributes to professional development and to the creation of better systems and processes in health care with the patient’s best interests in mind. Improvement knowledge helps practitioners to identify the gap between promises and what are actually done, and facilitates efforts to overcome these differences. Improvements in health care begin with recognising the need for change and that people/professionals have a willingness to change. However, implementing changes in large organisations takes time, which makes small-scale, local tests of improvements essential. Even though a change does not always lead to an improvement, the knowledge gained from failure is as important as knowledge gained from success (18). Implementing changes requires good planning to succeed. Four elements are identified in every process by “which 1) an innovation 2) is communicated through certain channels 3) over time 4) among the members of a social system” (19). Research shows that knowledge about implementation greatly improves the chances that an improvement is completed within three years (20). A succeeded implementation means that the change has become part of everyday work. When management and employees reflect critically on improvement outcomes and behaviours their knowledge develops from reproductive “single-loop” learning to a more creative, development-oriented “double-loop” learning (21, 22). To become a learning organisation, Senge highlights the importance of capitalising on people’s commitment and ability to learn on all levels in the organisation, not only management or a few selected employees. He also highlights the

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² INCA - Information Networks for Cancer; a national IT platform for the management of records on cancer patients regarding care and research. INCA is operated and developed jointly by the country's regional cancer centres.
importance of personal mastery as a keystone to the learning organisation. Personal mastery means that a person has a broad vision, and the ability to collect energy, develop patience and to see reality objectively.

When implementing improvements in an organisation, consideration must be given to the dynamics of the local context. Context is often defined as all factors that are not part of the quality improvement intervention (23). The result of the improvement initiative depends on how receptive the organisation is to change, what the intervention is, and how the implementation is realised (24). Many studies have tried to explain the variety of outcomes in quality improvement work. They have found that even when organisations were following an identical methodology with the same improvement goals, the outcomes were different (25). Whether an improvement initiative will succeed depends on contextual factors such as resource availability, team leadership, team skills, the microsystem motivation to change, the improvement culture and the capability of the microsystem (26). However, more research is needed on the conditions that influence successful intervention outcomes, and the time at which they should be executed (23). There is also a lack of knowledge which methods are effective within a certain context and if the results are generalisable (27). A research approach that combines qualitative- and quantitative methods can be used for further studies in this field (25, 28). One example of quantitative methodology that can be used is lean.

**Lean health care**

The lean methodology, also known as Lean Production, is derived from the Toyota Production System (TPS) (29). This systematic approach identifies and eliminates waste that is of no value to the customer. The approach is based on five principles (30): 1) Defining value to the customer 2) Identifying value streams that provide the customer with a product/service, 3) Optimising the workflow, 4) Customers get their product/service at the time they require, 5) Everyone pursues perfection. Lean thinking is about optimising the productivity and the quality of care, not by working harder but by working more efficiently and cleverly (29).

The principles used in Lean Production are designed to improve and manage processes and are widely used in health care. Both UK and USA started to implement the methodology in the early 2000s, and over 50% of the hospitals in both countries are working with continuous improvements that are lean-inspired today (31-33). In Sweden, the University hospital in Lund was the first to implement lean in 2007, aiming to increase productivity and quality for patients as well as employees (34).

Some examples of the tools used in the lean methodology are value stream mapping, root cause analysis (5 Why), A3 reporting, 5S and PDSA-cycles (Plan Do Study Act) (31). The four-step model was first developed by Walter A. Shewhart and is used to describe a process when implementing a change; allowing a learning experience for all the participants. The four steps are (30):

**Plan:** Identify an issue that should be improved, plan the execution and how data should be collected
**Do:** The plan is tested and all related results of the test are documented even those that were not expected
**Study:** Data from the predictions are compared with data from the test. The results are considered when planning for the next step. What have we learned?
**Act:** Action is based on what was learned. If the change worked, then it should be implemented in the daily working routine. If the change did not work, the plan is remodelled and a new PDSA-cycle is begun.

When organisations test and implement changes using the structure of the PDSA cycle, they learn if the change could lead to an improvement. Implementing a change in the organisation takes longer than performing the test cycles and cannot be executed until it is considered likely to be part of a new working routine (30). Langley et al. further suggest that implementation of new methods or routines could have three different approaches, depending on the complexity and the risks involved:

- The “Just do it” approach (or “cold turkey”)
- The parallel approach (implementing the change while the old system is still in place)
- The sequential approach by time (multiple components)

A branch that was developed from the lean-concept in the early 1990s is the Six Sigma. While lean focuses on workflow and processes, the main principle for Six Sigma is the quality and variability within the process (29). These two methods are often combined in laboratory management, like histopathology. Six sigma strive for a zero-defect rate in critical areas throughout the histopathology process such as poor fixation, specimen mix-ups, air bubbles and quality of the reports (35). While lean and Six Sigma focus on optimising the laboratory's own processes, there are also external factors that affect and concern histopathology.

**Current state of the histopathology process**

As a result of a shortage of pathologists in Sweden lasting many years, focus is often directed to the laboratory process of the patient’s treatment chain. In 2010, on behalf of the government, the Swedish Society for Pathology made an inventory of the number of medical specialists in the country (36). In their review they confirm that "the number of pathologists in Sweden in relation to population is half as many as in Norway, Denmark and Finland" (37). Furthermore, they found evidence that the workload had increased in the laboratories when the production of glass and paraffin-blocks increased by 29 % and 26 % from 2006 until 2009, respectively. The numbers are reflected in the increased TATs and patient waiting time. The increased sample inflow may be a consequence of an aging population and thus an increased number of sick people, but may also be because more and more ailments are counted as diseases and therefore require more resources (38, 39). Today’s pathology focuses on finding all pathological abnormalities, regardless of magnitude. Many of today's cancers also require treatment with target-specific drugs (40).

One example of increased sample inflow, which has resulted from poor guidelines, is the removal of benign skin biopsies (41, 42). The National Health Care program for malignant melanoma emphasises the importance of early diagnosis to ensure an opportunity to cure and suggests that the level of education among clinicians must be increased; i.e. with expanded use of dermatoscopy (43). This instrument helps to increase diagnostic certainty and reduces the proportion of unnecessary excisions.

In parallel with internal process improvements in pathology laboratories around the country, there is also a large national investment in digital pathology (DigiPat) (44, 45). The Department of Clinical pathology in the Region of Jönköping County is one of nine health care providers participating in a development project that started in 2012. Pilots have been initiated. The purpose of the project is that slides shall be diagnosed by a pathologist on a
screen instead of a microscope. Adapted image processing systems will facilitate the measurement of, for example, tumour size and the presence of certain cell types. The new approach will also improve the workflow in the laboratory and, among other things, involve substantial time-savings in the diagnostics of complex patient cases that require external consultation.

Internationally, many countries are investing in improving the availability and quality of cancer care. The Institute Of Medicine (IOM) has investigated how cancer care is delivered in the USA and has compared it to an ideal state from a patient perspective (46). They found a large gap between the current state and the desired mode of how patients experience cancer care, and are therefore implementing changes. In the past four years, the UK government has also made large investments in improving the quality and patients’ experience of cancer care (47). With funding they are hoping to improve outcomes for patients with cancer and get higher survival rates. The National Health Service (NHS) is working on quality improvements in the UK. Their aim is to build sustainable improvements across the entire pathway of health care. Pilots have been made to investigate whether it is possible to deliver reports on 95% of all histopathological samples within seven days with the use of lean methodology (48). The report shows that this could be accomplished but there are critical obstacles along the pathway that must be overcome in order to succeed. The pathway includes everything from transportation, dedication and leadership. By using lean methodology the NHS teams were, amongst other things, able to identify waste, test PDSA-cycles, make statistic charts and use data to demonstrate the impact of improvements (30, 48). For example, a university hospital in Leicester came to the conclusion after identifying waste, that 80% of the time the sample spent in the laboratory process added little value to the final product (49).

Local problem
There are a total of 31 histopathological laboratories in Sweden. The Department of Clinical pathology in the region of Jönköping County is one of 11 participants in Nysam; an organisation that compares key performances in health care (50). None of the members are university hospitals. Although only a third of the Swedish laboratories participate, the report shows how laboratories are performing in comparison to each other. The department in Jönköping has many referrals in relation to the county population but is underachieving according to the statistics presented in the report.

The goal set by the region Jönköping County is a mean TAT of seven days for histopathology samples; i.e. registration to report (figure 1). Historically, the actual mean report time is about 12 days, or that 50% of the samples are reported within 15 days (51). Today, the customers (referrals) make their own priorities for the report time, i.e. 1-3 days, 5-10 days and 10-20 days. When these promised report times are not kept, it leads to delayed diagnosis and treatment intervention for the patient. The local problem is that samples have long TATs across the laboratory process. There is also considerable variation in TATs between samples. This creates difficulties for the customers concerning when they should ask patients to return and receive information about their diagnosis. This leads to unnecessary anxiety for the patients. Patients often say that the worst aspect of waiting for a report is "the unknown". Long waiting leads to anxiety, depression and sometimes physical pain in patients with cancer (52). Whether the waiting time itself involves a medical risk or not, the patients and families are psychologically affected. In a Canadian study involving experiences of 218 patients with breast cancer, the predominant concern (72%) was related to the time between the first visit to a specialist and the time when they received their cancer diagnosis. Patients also expressed anxiety that the cancer had spread between diagnosis and time of surgery (53).
**Purpose of the QI intervention**

The purpose of the QI intervention was to deliver an effective and streamlined histopathology service with reduced TATs. By implementing a novel laboratory process the intervention should lead to a smooth process flow to avoid the emergence of so-called “outliers”; i.e. test results that for various reasons have a very long turnaround time. Reducing the TAT, i.e. the time between sample arrivals to report, will facilitate the planning of the next consultation with the patient and ensure that the treatment can begin as soon as possible. This will reduce the patients’ waiting time and the period of uncertainty. The specific goal of the QI intervention is:

By December 31, 2014:
- **reports on at least 90 % of all tissue samples should be made within 15 days**

The aim of the QI intervention was to build knowledge about laboratory processes to begin the establishment of a sustainable learning environment by using the model of Continuous Quality Improvement (CQI) as an inspiration. Communicating laboratory processes both in- and outside the department will build knowledge concerning patient’s waiting time.

**Study purposes**

The improvement work describes a QI intervention on how to deliver an effective and streamlined histopathology service with decreased TAT for histopathological samples. The purpose of the study was to create awareness of the crucial factors that contribute to successful QI interventions. The study questions are based on the Punch approach to how to develop effective research proposals (54):

- **How do staff perceive working with QI interventions?**
- **Which factors and experiences in QI interventions contribute to success versus obstacles?**
- **Does working with QI interventions contribute to new knowledge about patient’s, customers and co-workers?**
Method

Setting
The Department of Clinical pathology is part of the Division of Medical Services and is situated at the Region County hospital Ryhov in the region of Jönköping County, Sweden. The laboratory processes approximately 23 000 requests annually and receives samples from all over the region, which has about 340 000 inhabitants (55). Samples arrive from three hospitals; Jönköping, Eksjö and Värnamo and from more than 50 health care centres, five times a day by car. The laboratory is open during the daytime, Monday to Friday.

The laboratory has about 45 employees; eight pathologists, one resident in training, 19 biomedical scientists (technicians), five cytotechnologists, seven care administrators, one autopsy technician and two nursing assistants. The laboratory also employs external consultancies that helps to process some of the samples, mainly small samples i.e. biopsies and skin lesions. Before the samples are diagnosed they are processed in a comprehensive and time-consuming manner in the laboratory (figure 2). Specimen processing is mainly performed by technicians, followed by microscopy by pathologists and typing of the final report by a healthcare administrator. Depending on the nature and complexity of the tissue, TATs differ. Annually, the department also teach students. Most of them are technicians and the most intense period occur twelve weeks in the fall, from September to December (w 36-48). Three senior students attend the department for three weeks at the time. Historically, staff has regularly worked overtime to shorten backlogs.

Working in clinical microsystems is a tradition within the Division of Medical Services and the improvement work performed in the department has a lean-inspired team approach, including team co-ordinators and method specialists (30, 56). Each of the five microsystems has a team co-ordinator whose task is to inspire employees and gather information about the working process. Each microsystem, which is also a team, has its own whiteboard where new, on-going and completed improvement works are displayed. On-going measurements concerning the work performed by the microsystem are also visualised on this board. In the laboratory there are two main whiteboards that show a scorecard, maps of various laboratory processes, various production measurements and on-going projects. Each morning all available staff meet up for a five-minute stand-up meeting, where the day’s work load, activities and any absences are summarised. Regularly every month the whole staff meets up at a workplace meeting. In order to avoid taking too much time away from processing the samples, regular meeting forums have been used as widely as possible when working with the QI intervention. The department strives to arrange as many meetings as possible in the afternoons to adapt to the laboratory workflow.

Laboratory process at a glance
All pathology workflows include three phases; preanalytic, analytic and postanalytic (figure 2) (57). The preparation process of the tissue begins with formaldehyde fixation for at least 24 hours (preanalytic). Small biopsies fixate faster than large samples, which must be considered when working with QI interventions. It is not unusual that tissue samples undergo at least eight different sub-processes before the customer receives the final report; i.e. from registering the sample to a report being typed and sent (figure 2). The analytic phase begins with grossing and ends with typing of the report. To make a diagnosis it is sometimes necessary for samples to be further investigated using immunohistochemistry (58). This method helps in identifying proteins using antibodies that bind to specific antigens on the
surface of the cell membrane. Various cell types may thereby be identified, which facilitates the diagnosis and allows specific questions to be answered. All activities processing tissue samples are logged on the Laboratory Information System (LIS), Analytix from CGM (51). It is therefore possible to measure the time between different sub-processes within the total TATs.

Figure 2. Illustration of the main events in the histopathology process (preanalytic, analytic, postanalytic) from arrival of samples to reporting. Immunohistochemistry followed by diagnosis is not performed on all samples.

Design and method of the intervention

The laboratory aims to deliver an effective and streamlined histopathology service. Improvements relating to the internal processes are planned, managed and processed primarily by each team. In some cases improvement ideas lead to new investments. Four major backlogs have previously been identified in the laboratory process and in 2013 a number of improvements were initiated to improve the process, focusing mainly on two events; grossing and sectioning (figure 3).

Figure 3. Process map of the department, showing four holdbacks in the laboratory process as well as the two strategies of change and where in the process the AutoTEC was implemented.

With the aim of identifying and eliminating waste, a lean improvement approach was used (30). The employees working with the QI intervention had knowledge and experience of working with improvements and were familiar with some of the lean tools. To succeed with improvements and obtain sustainable results it was important to take advantage of the professional knowledge already existing among the staff. By showing the employees how the system worked and by visualising its variation; understanding and awareness among the employees about their own work process was built (figure 4) (17). During the QI intervention the author put much time and effort into building knowledge about the organisation as a
system; “system thinking” among the employees (22, 56, 59, 60). By visualising, for example variation, measurements, and talking about internal working processes in the group, the author facilitated a sustainable learning environment (CQI). To accomplish CQI the knowledge-building need to take place gradually and the success lies in elements such as quality improvement, employee empowerment, teamwork, plan and implement changes and the use of scientific methods to identify and address quality issues (61).

To further build knowledge and get into the learning- and patient perspectives, lectures were held during spring 2014. A local surgeon gave a well-received urological lecture, focusing on prostate cancer. The lecture concerned not only technical aspects of the samples, but also other information that would benefit understanding and collaboration between departments. The other lecture was held by a breast cancer patient in her 40s. The whole session was all about health care from the patient’s perspective, and she described her journey and how she coped with waiting and anxiety during her time as a breast cancer patient.

The QI intervention had four parts with the following objectives:

- To describe, plan and implement a QI intervention that may improve the laboratory process in order to get faster TATs.
- To visualise and communicate production, TATs and demands both within the laboratory but also towards customers that submit tissue samples. This had not been done before in this manner.

This part also included development and implementation of Diver, a new statistics program that is linked and retrieves information from Analytix. The system was customised and divided into two parts, one part directed externally to the customer and the other internally towards the laboratory process. By using the system, customers were free to develop their own customer-specific statistics concerning, for example, costs of analyses and/or what type of samples they had sent to the laboratory.

- To collaborate with customers with adapted information suitable for the specific customer. This was of importance in the improvement work in order to create a dialogue and understanding concerning patients’ waiting time.

- To learn if the patients’ waiting time changed after the QI intervention using the INCA registry for colorectal cancer patients. Also, observing written complaints regarding waiting time made by the customers was done.
QI intervention

Automatic embedding process

One time-consuming part of the histopathology laboratory process is the embedding of paraffin blocks. The laboratory produces on average 325 blocks each day, but on some days the production exceeds 500 blocks. The embedding process was previously executed manually by three technicians and usually lasted about four hours during each morning. Could this process be improved by new equipment? In 2013, only one embedding instrument was available on the market, the AutoTEC® (Automated Tissue Embedding Console) from Sakura, USA. In 2013, key persons from the department in Jönköping visited two other pathology laboratories in Sweden to investigate how they had incorporated the AutoTEC into their preparation process. Based on this knowledge the AutoTEC was purchased and installed in September 2013. The goal of the investment was to save time in the embedding process, making it possible to relocate at least one technician to perform other tasks.

During the learning period, the new method was more time-consuming in the grossing process, i.e. the tissue had to be oriented in the new embedding cassettes. The contract that was written with Sakura was a direct reflection on the production. The more that was produced with help of the AutoTEC, the more discount was received on laboratory consumables. The long-term goal was that at least 50% of the block production should be embedded with the AutoTEC in 2015 and 75% in 2016. To achieve this goal, PDSA cycles were made continuously (figure 4) (30). The process group led by the team co-ordinator worked continuously with the implementation of the AutoTEC using the PDSA cycle as a model for improvement. Each cycle was designed to answer specific questions related to the purpose of the specific PDSA-cycle (62).

Figure 5. The model of improvement (30).

Brainstorming, workshop and SWOT

In January 2014, all technicians were encouraged to come up with as many ideas as possible focusing on laboratory improvements and TATs when attending two brainstorming sessions. The “four rules of brainstorming”: 1) to generate as many ideas as possible, 2) to avoid criticising the ideas, 3) to attempt to combine and improve on previously articulated ideas, 4) to encourage the generation of unusual or wild ideas, were used as a guide (63). The sessions were held in each process group and every single idea was documented and displayed during the sessions. The choice of method was based on its familiarity among the employees.

To summarise and further analyse all ideas that arose from the brainstorming the entire group of technicians met again in a workshop session. A workshop has a specific purpose and is a good method to use when going from thought to action (64). This method is more focused on problem-solving and allows questioning of ideas. The group agreed on the suggestions for improvements that should be tested in February 2014.
In order to identify which pre-conditions existed to achieve the goal set for the QI intervention, a SWOT analysis was made in early February 2014 (65). The aim was to find strengths, weaknesses opportunities and threats connected to the QI intervention. The session was performed by the author, the management and two team co-ordinators.

**Novel laboratory process as a part of the intervention**

During 2013, several important changes in the work procedures were made that had to be accounted for in the planning of the intervention. One change in December was the implementation of the in-house method SISH (Silver In Situ Hybridization) for determination of the HER2 gene in breast carcinomas (66). The results of the diagnosis have a direct impact on what treatment the patient receives. HER2 is a protein found on the surface of most cells in the body. The protein regulates cell growth and mitosis. In HER2-positive breast cancer the cells contain an increased amount of HER2 proteins, leading to enhanced cell growth and mitosis (67, 68). HER2 testing is routinely performed on all breast cancer tumours and when positive a SISH analyse is made. Before 2014, the samples were sent to a hospital in Kalmar for analysis, which was time-consuming.

The laboratory work follows a six-week schedule and each day is divided into four blocks; two in the morning and two in the afternoon. When planning for the novel laboratory process starting on 17th February in 2014, all actions described before 2014 were taken into consideration as well as the new input from brainstorming, workshops and SWOT analysis. The goal was to free time from other parts of the process and instead focus on the two holdbacks; grossing and sectioning.

**Visualisation**

Visualisation as a tool was important in the work on the QI intervention. To serve this purpose, data was collected mainly from two systems:

**Analytix**

Most of the statistics used in this thesis derive from data that were logged in the LIS, Analytix (Laboratory Information System). No personal ID was used since the samples, once they were registered, were given a unique number that allowed tracking throughout the laboratory process. Most searches were done by using boundaries of morphology- and topography codes (table 1). These codes were supplemented with the dates 2013 and 2014 and narrowed down and limited to diagnostic rows 1. However, since the system had many limitations it was sometimes necessary to get detailed information by tracking data from individual samples (FISH and SISH). This was done after the morphology and topography search was performed. Each search in Analytix was very time-consuming. Data were exported to Excel for further analysis and visualisation in charts.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Morphology code</th>
<th>Topography code</th>
<th>Type of sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>FISH</td>
<td>Fe13*</td>
<td></td>
<td>302, 402</td>
</tr>
<tr>
<td>SISH</td>
<td></td>
<td>P33767</td>
<td>302, 402</td>
</tr>
<tr>
<td>Breast</td>
<td></td>
<td>T040*</td>
<td>302, 402</td>
</tr>
<tr>
<td>Colon</td>
<td></td>
<td>T67</td>
<td>10, 103, 303, 403</td>
</tr>
</tbody>
</table>

Table1. Description of the criteria used in the search for information.
In March 2014 a decision was made by the management that the LIS of the department should be linked to the statistic program Diver, an access point that allows customers to monitor their own requests and costs at any time. The system also allows the laboratory to monitor its own internal processes. Diver is customised in-house and therefore the author had the opportunity to be involved in the development of the interface. The first step was to develop the customer-specific section of the new system and to complete it, which then was launched in February 2015. The progress in developing Diver for internal laboratory use was intensified during the autumn of 2014. The author helped verify data between Analytix and Diver and therefore had the possibility to use some parts of the system before its release.

**Customer collaboration**

Preparations were made before meeting with customers. In these cases, customers were representatives from two of the clinics that submit tissue samples; the Department of Surgery (bowel) and the Department of Dermatology. The meetings were arranged during October – December 2014. Before the customer meetings, current mean TATs from the laboratory process were produced, shown and discussed as well as more specific TATs directed towards the customer. The goal was to create a dialogue with the customers on patient needs and how the Department of Clinical pathology could add value in relation to the current laboratory service provided, and vice versa. The new medical manager, who started to work on November 1 2014, also attended the meetings to gain a good insight on what improvements the laboratory had worked on earlier.

**Design, methods and analysis of the study of the intervention**

The design of the study of the intervention had a case study approach including both quantitative and qualitative data collection and analysis. Case studies can contribute knowledge about why some improvements work in certain contexts but not in others (25, 69). Since the laboratory process samples from 23 000 patients annually, not all tissues could be analysed further and included in this QI intervention. The selection was made from patients from the region of Jönköping County from whom tissue samples from the breast and bowel had been taken in 2013 to 2015; before and after the intervention. These two large groups of patients were chosen because their samples went through a complex process within the laboratory and reflected any acquired sub-optimisation during the intervention. Tissue samples from the breast have routinely been a priority in the laboratory because of the complexity of their diagnostic process. This priority did not change with the intervention. All collected data was retrospective and primarily focusing on patients with a cancer diagnosis. A baseline was produced in January-December in 2013.

**Quantitative assessments**

Evaluation of the improvement work was carried out primarily with quantitative measurements. To simplify the interpretation of the results it was favourable to illustrate the data graphically (70). The data in this QI intervention was mainly displayed dynamically, i.e. with run- or control charts (XmR) showing how data varies over time (71). Using dynamic displays helped in understanding the processes and whether additional collection of data and analysis were required. The “control chart decision tree” was used as a guide when deciding how the data would be presented (72). The charts were made in Excel, SPC XL and Statistica.
**TAT measurements**
In the past, the mean laboratory TAT for all histopathological samples in the region had been measured monthly and displayed on an X-S chart to the management and the employees on various occasions. This measure is also used nationally as laboratories compare their TATs with each other. Since this way of displaying and visualising laboratory mean TAT was familiar it was continued. The mean laboratory TAT baseline was illustrated from January 2013 to December 2014.

The goal set for the intervention (at least 90% of all tissue samples should be reported within 15 days) was measured monthly and presented both with a bar chart and with XmR (72). The number of histopathological samples reported within 5, 7, 10 and 15 days was displayed and demonstrated in a bar chart showing how TAT was distributed between different time intervals.

**Specific tissue TAT measurements**
For display of specific tissue TAT measurements, bar charts and control charts (XmR) were used. The bar chart documents a quick overview of the results but does not allow further analysis. Deeper analysis of colon resections were made by using XmR charts and box plots, which are a good way to demonstrate if the change has led to an improvement (62). In the XmR charts the stability, trends and outliers were visualised and analysed in the selected processes. The charts also supported identification of the incidence of random (natural) and/or systematic variation in the processes (72). For the analysis of the SISH method a frequency plot (scatter plot) was used which summarised the capability of the process performance (62). As the populations were not normally distributed a t-test could not be performed. Instead a Mann-Whitney test was performed. The date of reported FISH/SISH analysis was difficult to obtain because it was not logged with a specific name. For data collection, logs for each individual sample were studied and the log “supplements” made by two specific pathologists was used. Charts were made to display the results of these questions:

- Did the introduction of the SISH method to detect the HER2 gene change the TAT for patients with clear breast cancer?
- Did the TAT change for patients with breast cancer after the QI intervention?
- Did the TAT change for patients with colorectal cancer after the QI intervention?
- Did the TAT change for patients with bowel biopsies after the QI intervention?

**Driver diagram**
Before analysing the TAT measurements a driver diagram was made on colon resections (appendix 4) (73, 74). A deeper analysis was performed on colon resections because it became clear, working with this QI intervention, how important this process was for the patients. Three primary factors were identified that affected the goal; number of requests, time management and resources. To obtain data on resources, Heroma3 was used. This type of analysis is usually done before any QI intervention starts. However, in this case this method was used when the results were about to be analysed in order to determine which measures that had impact on the goal that was set.

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3 Heroma - a salary system with schedule- and staffing management
Implementing AutoTEC
The number of AutoTEC embedded blocks was compared to the total block production monthly. The measurement started in October 2013 and went on continuously.

Patient waiting time
To evaluate if the QI intervention had an impact on the patient waiting time the author requested help from authorised staff, searching the national quality registry INCA, concerning colorectal cancer patients. The data points (TATs) chosen in 2013 and 2014 were; time of surgery, pathology, medical conference (MDK), report to patient and start of treatment (figure 6). Because of the delay in receiving data from the registries, the possible effect of the intervention was not evaluated and included in this thesis. However, customers written complaints related to waiting times was measured and reported regularly to the department. These complaints were observed and noted during the time of the QI intervention.

Figure 6. Data points where the TATs were measured in order to study the patients waiting time.

Qualitative assessments
The study of the intervention included data from observations and semi-structured interviews performed in focus groups. A focus group usually consists of 6-12 members and the session lasts about one to two hours (75). This form of interview was based on open questions (within a specific topic) that were predetermined, and the opportunity to ask follow-up questions was provided (76). The participants also had the opportunity to ask specific questions not included in the interview guide, which encouraged and stimulated further reasoning (75, 76). One advantage of using a focus group was that there was a positive interaction between participants during the discussion, which gave rise to new perspectives and ideas to solve complex issues (77, 78). Another advantage of the method was that it allowed aspects that the researcher was unable to predict (76).

To explore and to find different aspects of the specific topic, participants from a range of professions were chosen (77). This type of group constellation served to highlight the activities involved in the improvement work from different perspectives. Therefore, colleagues with different professions, working at the Department of Clinical pathology, participated in the two focus groups. One group consisted of employees with a more senior position in the laboratory, i.e. team coordinators. The other group, comprised employees who did not have managerial positions. Each focus group consisted of five participants, which was an ideal number to let everyone have their own say and to minimise the risk of creating subgroups (76).

The date of performance of the focus group were checked with the laboratory manager, coordinated by the author and executed in February 2015 in an undisturbed setting. The semi-structured interview guide was inspired by the quality improvement framework 5Ps (56) with an additional 6th P for Passion. This framework helped to build more profound knowledge and awareness of the clinical microsystem and put the system (laboratory) in its context. The
open questions, derived from Purpose, Patients, People, Process, Pattern and Passion, were modified by the author to focus on quality interventions (appendix 1).

The author acted moderator in both focus groups and had a withdrawn role until only new questions from the interview guide was prepared (76). According to the Ethical Committee there was a benefit in terms of quality if the same person was the interviewer in both focus groups. Their reply to the application was that “the applicant advantageously can be this person in this project”4.

The focus groups were recorded and transcribed verbatim by the specific care administrator that participated in the focus group. An external observer also attended both focus groups and took notes throughout to ensure that proper documentation was made. To minimise the risk of identification by external readers, the respondents were encoded in the transcription. The interviews lasted for approximately 1.5 hours. To validate the recorded material, it was then listened through again by the author while reading the transcript and additions were made when it was a problem to hear the participants’ voices. By doing this, the author was able to compile more complete documentation from the focus groups (79).

The analysis of the focus groups was made inductively as a qualitative manifest content analysis (80, 81). The method focused on finding the visible, obvious meaning in the text. The transcripts were read through several times by the author and the texts were condensed into meaning units, codes, sub-categories and categories in order to answer the research questions connected to the QI intervention.

**Timeline**

The main activities included in the QI intervention and the study thereof were planned and executed as shown in the timeline below (figure 7).

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4 The Ethical Committee at the School of Health Science, Jönköping University, reference number 14-6.
Ethical considerations

Improvements in health care in Sweden are regulated by legislation (2009:400). Lynn et al. describe how both healthcare professionals and patients have an ethical obligation to participate in the improvements made, providing that the work follows specific ethical requirements (82). They also suggest that improvement knowledge can contribute to improvements in health care, but must be performed in an ethical manner. An ethical aspect that was recognised when working with the QI intervention was the use of resources in terms of working hours. The time spent on implementing the improvement work and performing the interviews could instead have been used in the work on patient samples. Collected data related to the patient’s waiting time and laboratory TATs was not considered as an ethical risk to the patient. However, there are national differences in patients’ waiting time and laboratory TATs, and that is not ethical. The collected data did not include personal information that could identify one specific patient or co-worker. Data from the QI intervention were stored electronically on a password-protected server and were only accessible to authorised persons working with the intervention, i.e. the author and superior management.

The study of the QI intervention was approved by the Ethical Committee at the School of Health Science, Jönköping University, reference number 14-6. Participation in focus groups was voluntary and could be ended at any time. The participants were informed both verbally and in writing about the aim of the study and written consent was obtained (appendix 2). Collected data from the focus groups were handled confidentially and were anonymised, i.e. person and profession when transcribing the text. The information will be stored for 10 years according to Swedish legislation (SFS 1990:782) before being deleted.

Result

This chapter summarises the results from the activities that were included in the improvement process. The presentation of the results is divided into two sections. The first section evaluates the goal “at least 90% of all tissue samples should be reported within 15 days”. The second section describes the results from the focus groups and answers the study questions; How do staff perceive working with QI interventions? Which factors and experiences in QI interventions contribute to success versus obstacles? Does working with QI interventions contribute to new knowledge about patients, customers and co-workers?

QI intervention

The QI intervention started in 2013 with the investment and implementation of the automatic embedding console, AutoTEC. Much time and energy was spent on the implementation. Then followed two brainstorming sessions and a workshop that resulted in several methodological changes to be tested starting 17th February 2014. To determine the dimensions affecting the result a driver diagram was also conducted on colon resections.

Brainstorming, workshop and SWOT

The two brainstorming sessions and the workshop that were performed by the technicians in December 2013 and January 2014 came up with many improvement ideas. The suggestions were summarised and the group agreed on which ideas should be tested starting 17th February 2014. The completed SWOT analysis that was performed in early February with the management did not add further new knowledge and indicated no restrictions in testing the novel laboratory process.
Novel laboratory process as a part of the intervention

The goal of the novel laboratory process was to free time from other parts of the process and focus on the two hold-backs; grossing and sectioning. The laboratory work, which followed a six-week schedule, with each day divided into four blocks; two in the morning and two in the afternoon, was not changed. The following changes were implemented from 17th February 2014:

- Two technicians instead of three were assigned to embedding.
- The grossing time, pathologist assisted by a technician, was limited to the morning (session 1 and 2).
- The technician that was in charge of the routine staining also handled special stains in the Benchmark Special Stains (Ventana Roche, Tucson, Arizona, USA).
- One consultant was hired to regularly work as a pathologist, two days a month.
- One technician started work in the cytology laboratory because of shortage of cytotechnologists. Before 17th February the cytology laboratory was staffed by a cytotechnologist.
- Two technicians started grossing during the whole day instead of earlier 1 1/4 technicians.
- Two nursing assistants took care of the receiving, unpacking and registration of samples, which previously was done by 1-2 technicians depending on incoming workflow.

One important step before making the described changes was to work off the backlogs. This was done on two occasions (weekends) a few weeks before the change. The effort covered the entire laboratory process and included technicians, histopathologists and health administrators. The effort was successful and the novel laboratory process began with a fresh start, from all professions’ perspectives.

When introducing major changes, it is important that all staff members involved have the opportunity to test the new approach before evaluation. One test period consisted of a six-week schedule. Every six weeks an evaluation was made, resulting in only small alterations and adjustments to ease the daily work (data not shown). In September 2014 the hired consultant (pathologist) extended his working time from two to four days a month.

Visualisation

All data supporting the visualisation throughout the QI intervention was collected from Analytix and Diver.

Diver

The finished product for internal use was launched in February 2015. Working with Diver was seen as an important part of the QI intervention, since the current LIS (Analytix) was insufficient for dealing with statistics. The author, together with the Diver project group, chose “check-points” through the laboratory process that could allow measuring between TATs (figure 8). Collected data from Diver was exported to Excel for further data analysis and visualisation in charts. The work with Diver resulted in a first version and the system can be further developed with additional “check-points” in the future.
Customer collaboration

Two customer meetings were held in November-December 2014; one with a representative from the Department of Surgery (bowel) and one with representatives from the Department of Dermatology. Mean TATs from the laboratory process were shown and discussed as well as more specific TATs that concerned the customer. The Department of Surgery said that they had noticed a big improvement in report time in 2014. The dialogue in the meeting was good and the surgeon thought it was interesting to take part of the laboratory internal processes. The Department of Surgery was rather satisfied with the TATs concerning bowel biopsies. However, they were still not satisfied with the TATs for larger samples such as colon resections. To begin treatment with chemotherapy they did not want the time to exceed 15 days from surgery to time of the multidisciplinary medical conference (MDK). This means that histopathology reports have to be produced even faster, since the colon resections often arrive at the laboratory one to two days after surgery. The representative from the Department of Surgery also stated how important it is for the patient that the report time is fast. In the worst case, chemotherapy cannot be initiated because the report is delayed. The Department of Surgery suggested inclusion of the MDK date on referrals for visualisation throughout the laboratory process. At the interdisciplinary regional meeting on 18th December an agreement was made that all three hospitals should specify the time of MDK on referrals5.

The collaboration with the Department of Dermatology had a slightly different content. The meeting mainly focused on the increased sample inflow of benign skin lesions. The Department of Dermatology suggested that the region should invest in dermatoscopes at all primary health care centres and to combine this investment with additional education. These efforts could help to increase the diagnostic certainty and hopefully reduce unnecessary excisions. The workload would then be reduced, not only in the Department of Clinical pathology, but also in other departments. The Department of Dermatology requested figures on monthly proportions of benign versus malignant skin lesions in the region for the past year6. This data could then be used in a parallel project that would require greater collaboration between the two departments.

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5 The monitoring and evaluation of how well this change was implemented in the process is not described in this thesis due to the limited timeframe.

6 The data is not described in this thesis due to the limited timeframe.
Results of the quantitative assessments

TAT measurements

The goal that was set for the QI intervention was that at least 90% of all tissue samples should be reported within 15 days by 31st December 2014. The Department of Clinical pathology managed a total of 23,410 requests in 2013 and 23,265 requests in 2014, respectively (figure 9). Seasonal variation was seen in the inflow of samples, with fewer requests during the summer months and peaks in the fall. Each request resulted in approximately 3.3 paraffin-blocks and 4.6 slides, representing the total workload.

The mean report TAT and the distribution of all histopathology samples are shown in figure 10. The bar chart illustrates the proportion of samples reported within 15 days, and the goal of 90% is included. In 2013 (baseline), a peak was seen during the summer months but without reaching the goal of 90%. In comparison, a higher proportion of reported samples within 15 days are shown in 2014 and 2015. Peaks are seen in March-April and during August-October 2014, however, the goal of 90% was not reached. The start of the novel laboratory process starting in 17th February 2014 is indicated in the graph. The secondary axis shows the mean TAT calculated in days (figure 10). In 2013 the mean TAT varies from 8.1 in August to 13.6 in January. The short mean TAT coincides with the higher percentage of reported samples. There is a large TAT peak in January 2014 of 14.1 and a big drop in March. The mean TAT in 2014 is generally lower than in 2013.
Figure 10. Distribution of reporting of all histopathology samples and mean TAT distribution (secondary axis).

The data illustrated above is also displayed in two XmRs (appendix 3). The first graph shows that the process is random with a special cause seen in December 2013. The graph also shows that a change was made in February resulting in ten data-points above the centerline until November 2014. In the second graph a shift has occurred, illustrating the start of the novel laboratory process. The XmR indicates a normal variation.

A bar chart showing the distribution of how samples have been reported between specific time periods is shown in figure 11. In addition to the higher proportion of reported samples 2014 compared to 2013, also shown in figure 11, the chart also illustrates that more samples are reported both within seven and ten days compared to 2013. The total proportion of all histopathology samples has increased from 54% in 2013 to 77% in 2014.

Figure 11. Distribution of how all histopathology samples were reported during different time intervals.
Specific TAT measurements – breast

*Did the TAT change for patients with breast cancer after the QI intervention?* The distribution of mean report TATs and proportion reported within 15 days of mastectomy and partial mastectomy are shown in figure 12 and 13. The start of the novel laboratory process is indicated in the graph. In 2013 (baseline) peaks were seen in January, April, June and August and low bars are shown in May, June and November (figure 12). A generally higher proportion of reported samples within 15 days could be shown in 2014 compared to 2013. November 2014 was the only month reaching 90%. The secondary axis shows the mean TAT calculated in days (figure 12). In 2013 the mean TAT varies from 14 days in June and September to 24 days in November. The mean TAT coincides with the proportion of reported samples. The mean TAT in 2014 is generally lower than in 2013 and varies between 11 days in June and November and 19 days in February. In 2013, The Department of Clinical pathology managed 138 requests spread over the year with a maximum of 23 in May. In 2014 153 requests were managed with a maximum of 23 in May.

The graph visualising partial mastectomy (figure 13) has a similar appearance as the graph for mastectomy (figure 12). The mean TAT from March 2014 and forward is generally lower than in 2013. The bar chart shows a peak when reaching the goal in June 2014. In 2013, the department managed 185 requests spread over the year with a maximum of 23 in April. In 2014, 140 requests were managed with a maximum of 19 in April.

![Figure 12. Mean report TAT (secondary axis) and distribution of mastectomy 2013 – 2014.](image)
Implementation of SISH

The effect of the implemented SISH method on TAT for patients with clear breast cancer (mastectomy, partial mastectomy) is shown in a frequency-plot (scatter-plot; figure 14). The analysis was performed using data from 62 consecutive patient samples from 2013 (FISH), which then was compared with 54 consecutive samples from 2014 (SISH). The median TAT for samples sent to Kalmar (FISH) in 2013 was 25 days, while the median TAT for SISH carried out in Jönköping was 15.5 days (p<0.001).
Specific TAT measurements - colon

Did the TAT change for colon (bowel) biopsies after the QI intervention? The distribution of mean TATs and the proportion reported within 15 days of colon biopsies are shown in figure 15. In 2013 (baseline) TAT peaks are seen in July – September and there is a huge dip in December. In 2014 the goal of 90% reported within 15 days was achieved for several months and also the mean TAT (secondary axis) was lower than in 2013. In 2013 the mean TAT varies from seven days in July to 21 days in December. The mean TAT coincides with the proportion of reported samples. The mean TAT in 2014 is generally lower and varies less, between six days in July to 16 days in December. In 2013 the department managed 1252 requests spread over the year with a maximum of 163 requests in October. The corresponding figures for 2014 were 1269 requests with a maximum of 142 requests in October.

![Mean TAT and distribution colon biopsy](image)

Figure 15. Mean report TAT (secondary axis) and distribution of colon biopsy 2013 – 2014.

Did the TAT change for patients with colorectal cancer after the QI intervention? The distribution of mean TATs and the proportion reported within 15 days for colon resections are shown in figure 16. At baseline (2013) a peak of the proportion of samples reported within 15 days was seen in February, and in 2014 peaks were seen in September and October. The goal of 90% was not reached at any time. The overall data is slightly better in 2014, but not as good as in the previously described tissues. In 2013 the mean TAT varies from 15 days in February to 30 days in December. In 2014 the TATs varies from 12 days in September to 25 days in March. In 2013 the department managed 95 requests with a maximum of 13 samples in May. The corresponding figures for 2014 were 110 requests with a maximum of 15 samples in October. In January 2013 and March 2014 none of the requests were reported within 15 days. Furthermore, a driver diagram was done on colon resection material (appendix 4).
Figure 16. Mean report TAT (secondary axis) and distribution of colon resection 2013 – 2014.

**Driver diagram colon resection**

The driver diagram that was made includes *TAT measurement, Distribution measurements, Preparation time, Diagnosis time, Recourses preparation staff, Recourses diagnosis staff* and *Number of requests* (appendix 4). The graphs illustrate data regarding only colon resections, except the last two illustrating resources. These two last graphs show total resources available in managing all samples and other work activities of the department.

The analysis illustrates large variations in incoming requests (1-16 each month) as well as in report time. It is difficult to demonstrate a clear pattern in the data that are presented. By studying the graphs a decrease in the variability in report time is seen in comparison with 2014. Larger inflows of colon resections do not seem to be directly related to report time. However, in December 2013 a correlation between report time, resources and diagnosis time was shown. A clear improvement can be seen in preparation time after the introduction of novel laboratory process in February 2014. The positive improvement seemed to have had a slightly positive effect, even on the diagnosis time.

**Patient waiting time**

The evaluation of whether the QI intervention had an impact on the patient waiting time could not be completed within the timeframe of this thesis. The author was unable to obtain the necessary data from the quality colorectal registry. The data that was presented from 2013 did not contain the specific measure points required in this thesis. To access that type of data, special authorisation was required. The reports from 2014 were expected to be published in June 2015 on the RCC website. The number of customer complaints concerning waiting times was reduced from 34 in 2013 to five in 2014. Three of the complaints were registered prior to February 17th, one in March 10th and one was a delayed consult report registered in April. The remaining of 2014 had no registrered complaints regarding waiting time.
Automatic embedding process
The results for how the teams worked with PDSA when implementing the AutoTEC are described with a few examples. The goal was set as: at least 50% of the block production should be embedded with the AutoTEC in 2015 and 75% in 2016. The implementation began in September 2013 and process improvements are still ongoing.

PDSA no 1:
**Plan:** The knowledge and experience gathered during the study visits to other laboratories, which were made prior to the investment, were the basis of the implementation. To validate the work process, the implementation started on a small scale with a few members of the process group. They included only large pieces of tissue in the embedding process with the AutoTEC.

**Do:** For the first evaluation one technician and one pathologist chose 50-60 pieces of tissue.

**Study:** The automatically embedded blocks were carefully inspected in the sectioning process by the technician, and stained slides were inspected in a microscope by the pathologist.

**Act:** Since the result was satisfactory the implementation was extended to include a larger number of blocks with the same type of tissues.

PDSA no 2:
**Plan:** Aim: all technicians should start using the AutoTEC cassettes when grossing. The goal was that 30% of all blocks should be mechanically embedded before 30th November 2013.

**Do:** All technicians had additional training in the handling of the new cassettes and started using them in routine work.

**Study:** In AutoTEC all data were stored and both the staff of the laboratory and the supplier could track the progress of how many blocks the device embedded per day. With the help of past statistics of the block production, the laboratory and the supplier reached an average production that served as a benchmark of production. There was some staff resistance to the implementation since the paraffin blocks required slightly different treatment during sectioning compared to the previous method. The staff also experienced that the grossing was more time-consuming. Furthermore, they experienced that some samples moved and that some tipped over when dehydrated/mechanically embedded. These samples (errors) were then manually embedded. The errors were noted in the production system Analytix, and the number of errors was negligible.

**Act:** The goal set that 30% of all blocks should be mechanically embedded was achieved (figure 17). The teams decided to continue working in the same way, shared their own experiences and encouraged each other to greater use.

PDSA no 5
**Plan:** Aim: 50% of all blocks should be mechanically embedded by 31st March.

**Do:** Worked as previous (PDSA 3) with the implementation. All technicians were using the new cassettes when grossing.

**Study:** The goal set that 50% of all blocks should be mechanically embedded was achieved (figure 17). One positive side effect seen was that technicians engaged in embedding finished this work one hour earlier than previously.

**Act:** The new routine was becoming well established. However, a slowdown in the positive trend was seen. How much did we dare to run? A decision was made to keep the former routine until further notice and discussed the progress with Sakura.
Results of the qualitative assessments

Focus groups were organised to answer the specific research questions: How does the staff perceive working with QI intervention? Which factors and experiences in QI interventions contribute to success versus obstacles and why? Has working with QI interventions contributed to new knowledge about patients, customers and co-workers?

Focus groups

The two interdisciplinary focus groups were performed over two consecutive days in February. The sessions lasted 1 hour 30 minutes and 1 hour 50 minutes. When analysing the material, six factors were recognised that had an impact on QI interventions. They are presented in alphabetical order: Competence, Compliance, Feedback, Interaction, Patient- and Customer focus and Recourses. The same categories were highlighted as important, but some aspects were emphasised to varying degrees between the two focus groups. The subcategories are presented with illustrating quotations below each category.

Competence

Competence, New knowledge and Dedication were three needs that the participants recognised as important in order to perform well and to be satisfied in their work. They wanted to feel competent and in control of their work situation. Furthermore, being able to take new initiatives to complete their tasks was even more meaningful. The desire for development was very strong in both groups and the positive energy displayed in the conversation concerning competence was very passionate. The participants showed dedication not only to individual development but also showed great interest in the department’s improvement as a whole.

Development

“…in order to streamline the work and improve it and at the same time as you might say, get a challenge for yourself…get the renewal of work…a mix of it…”

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Figure 17. Illustration of the total paraffin block production in 2013-2014 showing proportions of manually and AutoTEC embedded, respectively.
New knowledge

“...in order not to stagnate, to get ahead all the time, one is never finished, everything changes. We may change, approaches are changing, and there are new methods...”

Dedication

“...I have to develop. I can’t keep on doing the same skills all the time, I have to have a goal. When I reach there, I have new goals...”

Compliance

The sub-categories that comprised the category of compliance were Atmosphere, Attitude and Purpose. Both groups repeatedly mentioned that a positive atmosphere made it easier and more fun to work. They pointed out that a positive working climate stimulated them to try new things and it was easier to get “all on-board”. They also said that a positive atmosphere allowed more “errors” and those who were more hesitant about trying new things due to insecurities might feel more encouraged to participate. There were also many comments made on how hard it could be to overpower a negative person compared to a person with a more positive attitude to improvements. However, both discussions came to the same conclusion that all personalities add value and important aspects to the work, and that all input should be considered when starting something new. Different personalities may also come up with different kinds of improvements, which was seen as an advantage. Both groups also made several comments to the effect that it was much easier to get “all on-board” if the QI intervention effort had a clear purpose.

Atmosphere

“...then I think that you are motivated by and work better, when there is a good atmosphere... both within the group and the entire department...”

Attitude

“...the strange thing is that when making any improvement and there is someone who is very negative, then it is very difficult to overpower that person. If a person is very negative it affects everyone so much more in some way than a positive person does...”

Purpose

“...It’s easier to be motivated to do something new, if one understands the purpose...”
Feedback
Participants emphasised that it was motivating to receive feedback of various kinds, which is reflected in the sub-categories Evaluation, Reflection and Visualisation. The possibility to have time to reflect on the improvements that were in progress was considered to be an important factor that contributed to the success of QI intervention, and the connections with visualisation and evaluation were very strong. To regularly communicate data and results from QI interventions and internal processes was seen as knowledge building. The importance of making evaluations along the way was mentioned several times by both groups.

Evaluation
“...It's great trying new things and then making an evaluation. Not everything gets better, but then at least you have tried...!”

Reflection
“...that we at some point take a break and give feedback that this was actually good too...Look how much we have done that is good...”

Visualisation
“...it’s fun to see what happens with the sample and for the development, knowledge, and for us to get a better understanding...”

Interaction
The sub-categories that comprised the category of Interaction were Collaboration, Communication and Engagement. Both groups considered interaction to be one of the main contributors if QI interventions were to succeed. The importance of interaction was mentioned several times, and in particular, there were reflections concerning how communication and information should be distributed in the best way both within the department and from others. Comments were made that the communication between the different professional groups working at the department could improve. The groups also wanted to learn more about customer and patient needs and sought more collaboration. Team spirit and confirmation were also frequently mentioned and the conversation revolved around how much collaboration promotes improvements and benefits all involved. To benefit from improvements that others perform (customers, co-workers) was said to be inspiring and a great motivator to improve as an individual. Both focus groups agreed that they were not happy with the design and content of the stand-up meetings taking place every morning. Several improvements were discussed and the participants saw it as a good idea to form an interdisciplinary group that would work on improving the meeting.

Collaboration
“...It’s so important this with the collaboration and to obtain confirmation and to work together... it's a sort of confirmation that one feels involved in the group”
Communication

“...if the customer has requested something from the doctors, so that doctors have a new need, then communication within the department may be needed as well...”

“There is much potential for improvement in terms of communication...”

[between professionals]

Engagement

“It motivates me when other groups do something and have good results”

Patient- and Customer focus
Patient- and customer focus are summarised with the sub-categories Awareness, Demands and Responsiveness. Both groups had high patient awareness, and although the staff don’t physically meet patients in their everyday work, there was an imminent patient focus. In recent years governmental efforts to strengthen the role of the patient have been made and the word “customer” is used in many contexts instead of “patient”. Both groups were very reluctant to call the patient a customer. Both groups associated ‘customer’ directly with business and supermarkets and in the context of health care they felt more comfortable with calling referring departments for customers. It was also considered that the referring physicians acted as spokes persons for the patient and that it was therefore the referring physician who communicated patient needs and demands.

Awareness

“...I think the concept of ‘customer’ is questionable because you can choose to be a customer but you cannot choose to be a patient...”

...I think if you say ‘patient’, it sounds more like someone to care for, someone to help, someone to make healthy or healthier. Customer is a gentleman in a tie.

Demands

“...We have an obligation to keep up to date with all new that comes...”

“...it’s not we who invent the needs...it’s the referring physicians who show how much need there is.

Responsiveness

“...it’s important to think that behind every PAD number [request] there is an anxious patient... a human being...”
Resources

Resources are summarised in the sub-categories Capacity, Management and Quality. The participants noted challenges working with improvements at times when there were shortages of staff. They also noted that it was harder to deal with new methods when the workload was high. This made it easier to fall back on old working methods. The fact that the department was dealing with human samples, concerns were raised that shortage of staffing combined with improvement work could lead to stress and affect the quality of work which in turn could lead to serious consequences. It was rare that a tissue sample could be retaken; it had to be correct the first time. Only a few comments were made that someone should be in charge of the QI interventions. Depending on the extent of the intervention, this was not necessarily someone from the superior management; it could be done by a co-worker.

Capacity

“...that anyone does not begin with any major changes, like in the summer when there is a shortage of staff. Then you must deal with all that stress...”

Management

“...you have to be able to go to someone when there is a problem as well...there must be someone who can manage it...”

Quality

”...there cannot be errors either...it’s not so easy just to throw yourself out there and try something new because we are not supposed to make mistakes...there will be consequences...so you have to think twice maybe...”

Discussion

In this chapter, the interpretation of the results from the QI-intervention and the study thereof are summarised. The chapter includes relations to other studies as well as limitations, implications and suggestions for further research.

Results

The goal of the improvement work was to report at least 90% of all histopathology samples within 15 days. The QI intervention shows that although the original target was not accomplished, it was effective to apply lean-inspired methods, system thinking and the framework of CQI to shorten TATs. Working systematically with lean methods in a department of histopathology led to improvements. This has also previously been shown in other studies made in other histopathology laboratories, for example, in UK and the US (48, 49, 83, 84). The results of the QI intervention showed a general increase in the proportion of reported samples from approximately 50% to about 80%. An overall improvement was achieved for all samples included in the study, but the goal of 90% was only reached for colon biopsies. Despite this, the QI-intervention is seen as a success story for the department, customers and patients.

Some of the results include all samples and are displayed in monthly graphs at group level. This means that there is a mean value shown in most of the graphs. Appendix 3 shows the
proportion of samples reported within 15 days and illustrates an unstable process with a special cause in December 2013. The author has tried to identify what caused this outlier, but has not been able to identify a specific incident, which is common in a complex system. A possible cause could be a mixture of lack of resources and the type of samples that were submitted to the laboratory at that specific time. December is a month that contains many holidays and a substantial number of the staff members were on vacation. This may have implications for the laboratory production. In the same Xmr chart the implementation of the novel laboratory process in February was be seen, with 10 consecutive points above the centre line, which confirmed that the process was improved and was more stable (systematic variation). An initial improvement of the TAT was expected in February as the backlog had been worked off. However, that the change would lead to a sustainable improvement over time was uncertain. The sustainability of the QI intervention was tested in autumn 2014 when heavy workloads occurred at the same time as students' practical training. The difference this year compared to previous years was the non-building of backlogs. The preparation process was very streamlined and the atmosphere in the laboratory among all staff was positive. There was even room for the technicians to help in an external laboratory with sectioning. The relief effort was made on a dozen working occasions during the month of October; an effort that in previous years was necessary to work off backlogs. The time period that has been measured (2013 – 2015) shows that the inflow of samples and production was seasonal. This was not surprising given the holiday season. To investigate the time intervals during which the samples were reported, an additional graph was made (Figure 11, page 21). This proved to be very informative and was received positively by the Department of Clinical pathology. The improvement that took place between 2013 and 2014 was very clear and showed that most samples in 2014 were reported between seven and 15 days. To shorten the TATs further requires that a larger proportion of samples are reported within seven days. Based on available resources, the system is not fully optimised today. To achieve this, continued identification of waste must be made, since this will streamline processes. This could mean a review of existing resource utilisation of the equipment as well as investment in new equipment that may result in more efficient methods and workflows. Redistribution of the staff’s working hours from Monday to Friday could also be a way to better use the equipment. However, working weekends takes staff from the dayshift when surgical operations require the department's services and would increase the total number of staff needed. To adapt staffing to the inflow of samples is difficult; however, the sample inflow can to some extent be predicted and planned for. This ensures that the "right" person is doing the "right" working activity. Management may also grant vacation adapted to workload. However, the national shortage of pathologists would still be a barrier to shorter TATs.

Breast

As described earlier, breast cancer patients were given priority due to the complexity of their diagnostic process. Since this priority did not change in the context of the QI intervention, the outcome was even more interesting. Despite the fact that nothing really changed with these processes a clear improvement was seen between 2013 and 2014, both in terms of the proportion reported samples within 15 days and the decreased mean TAT. The number of incoming requests for mastectomy and partial mastectomy together, was about 30 fewer in 2014, which could have affected the outcome. The breast cancer process was chosen to see if any unwanted sub-optimisation occurred during the intervention. An Xmr chart to illustrate the variation in the breast processes was therefore not made. The charts show an improvement of these two processes and may therefore indicate that the improvement was made at the expense of other samples. However, this cannot be established. A stratification of all samples has had to be done to investigate this further.
SISH
The significant decrease in TAT when converting methods from FISH in Kalmar to SISH locally was expected (p<0.001). Kalmar did not perform FISH analysis on a daily basis, which led to batching affecting TATs negatively. Also transportation of samples and reports must be included in the calculation of the waiting time. The scatter plot showed that the mean TATs decreased from 25 days in 2013 to 15.5 days in 2014, but it also showed that the variation in TATs was quite large. The exact time point of FISH and SISH reporting was difficult to obtain because they were not exactly logged and could be a source of error. The data presented in the plot are therefore not completely reliable.

Colon
Colon biopsies are very small (1-3 mm). The preparation process is shorter and the sample volume is larger compared to the other tissues included in this QI intervention. As in the previously described results, the change has led to an improvement in TATs, and the target of at least 90% reported samples within 15 days was accomplished in several months in 2014. A positive result was expected; however, achieving the goal could not be taken for granted. While working with the QI intervention, information was revealed demonstrating how important the process was for colon cancer patients. Because of that, the author chose, besides the “standard graph”, to make a driver diagram on colon resections (appendix 4). The deeper analysis resulted in graphs of TAT measurements, inflow (requests), variation (box plot), preparation time, diagnosis time and resources (appendix 4). The results for colon resections were the worst of the samples included in the QI intervention, which was alarming. Although an improvement was seen in 2014 compared to 2013 it was not as clear as in the previous examples. Could the improved results of the breast process be at the expense of the colon resection process? Deeper analysis showed that the variation in TATs decreased in comparison with 2013, but there were too many samples exceeding 15 days. The graphs clearly showed that the diagnosis time was longer than the preparation time, i.e. the time of diagnosis was longer than the time it took to process the samples by the technicians. What causes the variation of requests must be discussed with the customer concerned. One of the principles of lean methodology is to strive for uniform workflow and it should begin with the number of requests. After the QI intervention was introduced in February 2014, a clear improvement and stabilisation of the preparation process with ten consecutive points below the centre line was seen. The improvements that were made were primarily focused on this part of the process, and the novel process reflects the result. The distinct outlier in preparation time in December 2013 may be due to fewer resources, combined with the fact that the inflow of larger specimens was higher (data not included). To get a complete analysis of the resources required in the colon resection process, a value stream mapping should have been made, i.e. a time/sample. As this was not possible within the timeframe of this master's thesis, the staff’s total working hours (resources) were studied. The pathologist resources used for diagnosis have less variation than the technicians’. However, note that they were fewer, and their absence had great impact on the TATs. In December 2013 a relation was seen between the various parameters in the driver diagram. Apart from that specific occasion no clear link between the parameters was discovered.

AutoTEC
The measures made before the investment of AutoTEC seemed to have had a good effect on the implementation. The positive development has now reached a plateau phase and discussions are on-going with Sakura regarding development of new embedding moulds. The new requested design should be adapted to core biopsies from the prostate, because they represent a large portion of the samples. The development of a new system takes time but is
necessary to reach the 75% target that is set to 2016. The target of 50% for 2015 has already been fulfilled. Since the PDSA is a cornerstone of improving knowledge the choice of method for the implementation of AutoTEC was rather obvious. The goal was to implement new equipment, with preserved high quality standards, in the routine work with the intention of reallocating resources. In order to detect and highlight any deficiencies, proposed changes were tested on a small scale before including more samples and employees. The changes were tested, measured over time, and the results were analysed and studied continuously (30, 56). The strength of PDSA is that the method is adaptable and can be used in both small and large contexts. In the UK for example, the PDSA was used in work on standardised care processes, and positive results were achieved. The four areas for improvement that the study teams were working with were the patient journey, the experiences of patient and care, delivery of care, and capacity and demands (16). The 43 teams managed in different ways to increase accessibility for patients and cut waiting times by over 50%, which is an encouraging figure when Region Jönköping County faces a similar challenge with its standardised processes.

**Patient waiting time**

Although a total evaluation of the patients’ waiting time cannot be made in the framework of this thesis, the outcome of the QI intervention should still have led to shorter TATs for the patients (figure 18); both in terms of shorter report TATs to the patients and also less time before starting the treatments. However, one positive effect was that customers’ written complaints about patient waiting times were reduced during 2014 compared to 2013. This meant an improvement from a medical point of view, but it also shortened the patient's psychological suffering caused by uncertainty (52). Previous research shows that uncertainty is what creates the most anxiety for the patient and can lead to depression.

![Figure 18. Data points where TATs could be measured in order to study the patients’ waiting time.](image)

**Visualisation**

The implemented QI-intervention focused mainly on the preparation process. If major changes had been implemented throughout the whole laboratory process it could have been difficult to identify which changes led to improvements (30, 56, 70). However, by visualising the processes and learning more about them created an atmosphere of openness and awareness among employees. More focus turned to the department's various production measurements and a curiosity was awakened to learn more about the processes, which was also expressed by members of the staff during implementation and in the focus groups. In their professional roles, employees had different pre-understandings of statistics, charts and graphs, which was a challenge. The aim of the visualisation was to involve as many employees as possible in the learning environment. Displaying various types of data and graphs supported the “system thinking” and understanding in the learning process. Visualisation is not only about collecting and organising data; the challenge is to communicate the information in a way that gives all staff involved the same understanding. Visualisation is a tool that helps to expose myths and theories about work processes and replace them with facts on how different parts of the whole process contribute to the final product (85). Many managers are good at collecting and organising data, for example, mapping and value stream mapping, but the visualisation
process often ends there. The Department of Clinical pathology has a tradition of displaying all kinds of data on boards, but has not historically used them fully to achieve a learning environment including profound knowledge and double loop learning (21, 22, 30). If managers are not fully committed throughout the QI-interventions there is a risk that future projects will be undermined and a general resistance to change may occur (85). To repeatedly start up new projects without pursuing and achieving previous goals can lead to resistance and weariness towards change among participants (22, 30). It could be hard to encourage employees to participate in future QI interventions when they remember that nothing happened the last time. Tullberg sees the role of leadership as a relationship between the leader and the led, and that it is the led that control how the activities are conducted, through their requirements and expectations (86). Senge and Angelöw believes that people who have expectations and who are often disappointed develop a cynical attitude towards change (22, 87). If the experience of the changes implemented earlier was negative it affects the willingness to try again, and vice versa.

**Customer collaboration**

Showing that the service provided by the department was relatively stable in terms of TATs was important. The customers needed to see that the improvement effort was not just a coincidence. The departments had to know the state of service that was currently being delivered. Good collaboration with customers is required to create an optimal patient journey through the healthcare system. Insights of the customer in the pathology process are needed to minimise misunderstandings concerning the meaning of TATs. The laboratory recognises TAT from registration to report, whilst the customer recognises TATs as the time from surgery to when they have received the report. This difference was observed when meeting with the Department of Surgery, and contributed to the fact that it was even more difficult to achieve their TAT expectations. Finding an effective way to communicate delayed reports before the date of MDK’s is a logistical challenge, but is crucial from both a customer and patient perspective. In today's information society, it may seem strange that communication is a challenge, but provision of this type of information should be automatic and should be supported by IT systems to limit the use of manual resources. Zarbo et al. confirmed in a study conducted in 94 US pathology laboratories that customers had great confidence in professional competence, but wanted improved communication (88). Zarbo’s study included how communication of the reports was conveyed. Powsner et al. studied this subject further and concluded that 30% of surgeons misunderstood the pathologists’ reports (89). To solve this problem, he suggests protocols and checklists for malignant diagnoses, and streamlined report formatting that will include the information demanded by the cancer registries.

The goals set by the customers sometimes seem unachievable, which makes it even more important to discuss and learn about the processes. Customer satisfaction is all about expectations and the quality of the final product (70). Different customers/patients may have different needs, which means that laboratory services might require more flexibility and compliance towards different demands; reflections supported by Novis (90). This way of thinking is very much up to date with the demands and implementation of standardised care processes (91). Laboratory TATs are important for customer satisfaction but they need to be aware of the factors that prolong the TAT. Patel et al. suggest that in addition to consulting, the number of slides and the use of immunohistochemistry, the diagnosis of malignancy is what takes time (92). Their study shows that the pathologist, understandably, needs extra time to think about a cancer diagnosis, and that this factor alone significantly prolongs TATs.
When implementing improvement in an organisation, consideration must be given to the dynamics of the local context. Even the way that the improvement initiative is implemented could be crucial to the outcome (19). Previous research shows that using the same methodology and having the same goal does not automatically mean that the result will be similar (25). Whether the improvement initiative will succeed depends on various contextual factors described by Kaplan et al, including resources, leadership, team skills, culture and the motivation to change (26). However, just identifying these components is not enough. The difficulty is to describe the way in which they interact with each other. Bate suggests case studies and/or action research as great ways to explore these relationships further (25). The combination of quantitative and qualitative research adds value. In this study, the author chose to combine quantitative measurements with focus groups.

**Focus groups**
The semi-structured interview guide was inspired by the quality improvement framework 5Ps, with an additional 6th P for passion (Appendix 1). The transcription and interpretation of the two focus groups generated six categories and 18 subcategories that describe factors which are important when working with QI interventions. The categories are Competence, Compliance, Feedback, Interaction, Patient and Customer focus, and Resources. Because the focus groups had the same contextual precondition, participants were selected according to their profession and professional capacity to ensure different perspectives. Despite this, the essences of the focus groups were the same.

Both groups agreed that it was easier to test new ideas for improvement and to adapt to new working methods if there was a clear purpose. The motivation increases if everyone is involved in the process and the goals are meaningful. The group atmosphere gets better, which contributes to a positive work environment, which includes security and stability. Prior research has shown that social contacts in a group are very important in the process of change, and contribute to the security that is required for a group to work well (87). A certain frustration against people who are extremely negative towards change emerged in the focus groups. It was pointed out that the negative attitude felt more "contagious" than the positive. After discussion, the groups nonetheless concluded that input from all individuals, even those who were recalcitrant, was important. Ideas from the different personality types provided different approaches to improvement. The perceived recalcitrance may be a result of a person’s past experience, but may also be due to their uncertainty about their own skills (21, 22, 87).

The desire for development was very strong in both groups. The participants showed dedication not only to individual development but also showed great interest in the department’s improvements as a whole. In prior work, Varkey et al. have presented that healthcare employees were more satisfied and more productive in organisations that had implemented clinical microsystems (5P). Even the quality of their delivered work was higher compared to organisations that did not implement clinical microsystems (93). The motivation to change was strengthened if the participants received regular feedback. To occasionally be reminded about the purpose of the change and its developments, preferably visually, was observed to be very positive. Something that participants lacked was more time to reflect on the effects that the changes had had on their daily work. Despite the fact that the groups repeatedly mentioned the importance of making evaluations, they felt they did not take the time to do this. They chose to prioritise other duties instead.
Interaction is one of the main requirements for a QI intervention to succeed. The groups wanted to learn more about customer and patient needs and sought more collaboration. In the context of standardised healthcare processes, increased collaboration is paramount. Both focus groups agreed that the communication between the different professional groups working at the department could improve. They did not come up with a solution to the “problem” but agreed that they appreciated the focus group setting and submitted that interdisciplinary collaboration contributed to increased learning about other people's work situation. Prior research shows that interdisciplinary teams are better placed to solve complex problems, and can do so more efficiently and with a better quality outcome (94). To benefit from improvements that others (customers, co-workers) make was highlighted as an inspiration and a motivator to improve even as an individual. Even though the staff members did not meet patients physically in their daily work, their empathy with patients is high. The desire to do the best for the patient was evident and acted like a strong motivator. The term ‘patient as a customer’, however, was not popular and the groups preferred to call the referring physicians ‘customers’.

In addition to individuals who are opposed to change; the challenges of working with QI interventions occurred during periods when the workload was high. There was not enough time. The participants also expressed concern that, in stressful situations, they would cause errors that could affect the quality of the samples. Surprisingly none of the groups talked much about leadership responsibilities in the context of QI interventions. They felt that it was good that "someone" should be in charge, but did not develop those thoughts further. Whether this was a true belief or simply an aspect that did not derive to discussion in the focus groups is unclear. The literature highlights leadership as a crucial factor for a QI intervention to succeed (22, 26, 30, 56, 85, 86, 94).

A number of factors are considered important for an improvement project to be successful. The categories that summarise the results of the focus groups show that the conditions exist for the long-term success of CQI. Groups' perceptions about which components are important when working with improvements are supported by previous literature (17, 56, 61, 95, 96). To accomplish CQI the knowledge building must be done gradually. However, it is not the knowledge of the individual that drives change forward; it is motivation. As long as the commitment and motivation is kept alive, the energy and drive to implement change will continue to exist. From a management perspective the recipe for success could therefore be to focus on and encourage those individuals who want to grow. Angelöw states that the motivation will be strengthened when a change gives the individual the opportunity to develop his/her skills or improve personal development, or when the change will create more responsibility and freedom at work (87).

**Conclusions**

- Working systematically with lean-inspired methods, system thinking and CQI framework leads to shorter TATs in a department of histopathology.
- The investment in AutoTEC reallocated resources and contributed to the success of the QI intervention.
- Management support is important and necessary to create CQI in an organisation.
- Dedicated and motivated staff facilitate the implementation of improvements.
- It is of great importance to encourage personal competence and development.
- Communication and visualisation are key factors that contribute to new knowledge about patients, customers and co-workers.
To succeed with the implementation of QI interventions, knowledge and understanding of contextual inequalities are important. Changes to be tested, should be redesigned in a way that respects local context.

The two interdisciplinary focus groups revealed six factors that are important when working with QI interventions; Competence, Compliance, Feedback, Interaction, Patient and Customer focus, and Resources. The lack of resources and people who are opposed to change may prevent the development and implementation of new improvements.

Method

The design of the study of the intervention had a case study approach, including both quantitative and qualitative data collection and analysis. The study was conducted at the Department of Clinical pathology at a county hospital in Sweden. Case studies can help to provide knowledge about why some improvements work in certain contexts, but not in others (24, 66). Both Bate and Baker say that it is not certain that either the approach or the results are transferable to other hospitals - this depends on contextual elements. The participants at the Department of Clinical pathology had some prior understanding of lean methodology and were also used to working with improvements. This was a strength and facilitated the implementation and the lean-inspired approach. Lean does not work for everyone and the use of the lean toolkit does not automatically lead to improvements (97). Kaplan et al. also concludes that leaders in a lean culture need to go from being problem-solvers to being coaches building learning teams.

The improvement tools used in the QI intervention were known by the staff previously which facilitated the work. Brainstorming, SWOT, workshop and PDSA are tools that are highlighted as important to increase understanding of the employee's own work and how it can be improved (98). The data included in the study was collected retrospectively, mainly from Analytix, but also from Diver and Heroma. The quality of the data is determined by how well a measurement is able to provide the same results on repeated measurements, i.e. its reliability. The degree to which it actually measures what you want to measure, indicates validity (71). Data retrieved from Analytix and Heroma are more reliable than data from Diver, because Diver uses Analytix as a source. The work with the QI intervention mainly used already existing information channels and meeting forums, and those worked well. Only a handful of additional meetings have been used which have involved other employees.

Strengths of the study are the long time period and the large number of samples that are included. The large amount of data has provided reliable information on the processes, but has also led to certain difficulties concerning the way the data should be presented. The advantage of having a laboratory production system is that all samples and many activities are logged and can be retrieved retrospectively. This has given the possibility to view data from all of 2013 as a baseline. Due to this, seasonal variations in both sample inflow and work effort have been detected in comparison with 2014. Another strength is that the author has been able to search and retrieve data from Analytix, which has increased the understanding of causality and how to determine the reliability of data. The data concerning FISH/SISH is not entirely reliable because of search restrictions in Analytix (LIS).

Meeting with more customers added value to the work. The thoughtful preparations combined with difficulty in scheduling meetings with customers delayed the work. Lack of time also made it impossible to evaluate the improvement initiative where time of MDK was noted on
the referrals for patients with colon cancer. This initiative was not part of the original design of the QI intervention, as well as the request that the Department of Dermatology made regarding malignant skin lesions.

Compared to sequence- and run charts, the control chart (XmR/ImR) enables more advanced analysis of data since it includes statistical rules for what is random- or systematic variation (71). The control chart is a kind of time-series graph having an upper and lower control limit and a centum line (mean). Measurement points within the control limits indicate a random variation, while measuring points outside the control limits signal a particular cause or systematic variation (60). Due to the amount of data included in this study, XmR charts displaying the mean value were chosen. The downside of XmR versus ImR is that the individual samples disappear (60). When working with improvements in an organisation, the ImR chart is preferable because it shows processes in real-time. A stratification of all sample types should have been done, or at least groups of samples, due to their different psychological characteristics such as size and structure. It should be noted that the fact that the measurement points appear inside the control limits does not automatically mean the results are satisfactory. The variation may be unacceptable depending on the performance that is measured compared to the goal set by the organisation. The actual variation is not displayed in an XmR chart but because of the sample volume included in this QI intervention this type of chart was chosen.

The driver diagram of colon resections includes limitations. The driver diagram displays total hours worked. However, the author had the possibility to split the time between the preparation staff and the pathologists, which resulted in two graphs. This information added value. Other members of staff were excluded. Also, a value stream analysis on colon resections had given more accurate information regarding time per sample. Driver diagrams, or at least control charts, should have been made on individual sample types to follow variation (ImR). These should be stratified weekly to monitor production statistics in real-time.

The two focus groups were interdisciplinary and worked together. The different professions contributed different perspectives on the specific topic and because they were also colleagues, they could more easily relate to each other's comments (77). This may have contributed to increased interaction among the participants. The author was aware of the risk of hierarchical disparities, but this was not observed.

The author acted as a moderator in both focus groups. The interview guide was semi-structured which meant that the moderator had a withdrawn role except when new questions from the interview guide were prepared (76). Considering the design of the focus groups, the discussions were not significantly affected by the moderator. However, the role itself makes it impossible to have no effect at all (77). The design was also strengthened by the approval of the Ethics Committee who argued that no dependency existed. The recorded material was transcribed verbatim, which strengthened reliability. To validate the transcript, the author listened through it again while reading. After analysing the material, the result was validated by the same external observer who participated in both focus groups.

This study contains a description of context, the selection process, and the analysis process and even displays quotes that support the interpretations. This, together with the relation to other academic studies within the field, increases the study's credibility (76). The collected material is limited and statistical generalisations cannot be drawn. Therefore, readers have to
determine the study’s transferability to their own context (76). Although the analysis of the focus groups was conducted inductively with qualitative content analysis, there is always room for interpretation. The author's prior understanding of CQI and success factors may have affected the results.

Working on this project has meant that the author (technician) has alternated between multiple roles; employee, colleague, student, improvement leader, coach, facilitator, moderator, researcher and the person compiling all the data. Since the author did not have an obvious leadership role it was preferable that the QI intervention was supported and authorised by the top management. The open management support has made it easier to promote and to visualise the QI progress in workplace meetings. Batalden et al. suggest that leaders who support and value learning in their organisations will speed up the process of improvement (17). The opportunity to show and discuss various aspects of the internal processes was continued even after 31st December 2014, but not to the same extent as before. The time that the author had reserved for preparations for the QI intervention (measurements, making graphs etc.) has instead been allocated to writing this thesis. Now, five months later, the mean TAT of all histopathology samples has slightly increased again and the energy that the employees previously showed towards their work has decreased. This could be a result of absenteeism due to the flu season, but may also be a consequence of the lack of CQI (figure 4 page 9) (17). This theory cannot be proven and is only a reflection made by the author. To achieve CQI takes time. However, the author’s reflections are supported by literature in that the department would benefit from having someone who “keeps the flame alive” (98). Organisations that are working with continuous improvements benefit from having a facilitator to keep the improvements up to date and push them forward. At times when there is a heavy workload, it can be hard for employees to remain innovative and motivated at all times and there is also a risk of change weariness. At these times, it is especially important that managers, at all levels, devote time and effort to showing how important improvements are. The learning perspective as a part of the improvement process will benefit the laboratory processes in the future. Both management and employees learn about the processes and see them with different eyes. Enhanced visualisation leads to new insights into the opportunities and limitations of the system. Workers closest to the microsystem usually know best how to improve it (17). The author’s approach in the improvement process towards team coordinators and employees has primarily been to act as a support, a sounding board. In order to avoid the author "owning" the project, pre-existing meeting forums have generally been used. Questions, new input and new approaches have been carefully prepared by the author with the aim of leading but not controlling. The goal was that employees should be self-motivated, be able to see the context, and connect improvements to the QI intervention.

The QI intervention has not had a project budget but has entailed increased costs in terms of investment in both equipment and staff. New equipment involves training and implementation, which in itself demands staff resources and time being taken from other duties. The laboratory process involves many manual steps. This makes the process sensitive to individual differences in terms of experience and work pace. These differences are difficult to control. The laboratory must therefore strive to find the tools and solutions that streamline and facilitate the daily work. The investments made in association with the QI intervention meant an improvement in both the work environment and the shorter TATs.
Databases and search terms used:
Medline, PubMed, Science Direct, Emerald, Cinahl, Cochrane
histopathology, lean, turnaround time (TAT), patient waiting time, improvement work, interdisciplinary, motivation factors

Implications for practice
The tools and methods used in this QI intervention were perceived as good by the author, when implementing the improvements in this specific context. In order to enhance the understanding and reach consensus about the clinical processes that affect patients, customer collaboration should continue and even involve customers other than those that have been included in this intervention. Visualisation should also continue in organised forms both inside and outside the department in order to build knowledge about the laboratory processes. The interdisciplinary co-operation within the department also needs to proceed. There are existing interdisciplinary methodology- and professional meetings, but they should be supplemented by temporary configurations that discuss specific areas of improvement.

The work on identifying waste in all parts of the histopathological process should continue in order to achieve an efficient and streamlined workflow with shorter TATs. This intervention has focused on the first part of the histopathological process - the preparation process. The driver diagram shows that this process is more stable than the diagnosis process and that there is room for improvement. Examples of improvement initiatives in the diagnosis process are protocols and checklists for certain diagnoses.

There is also room for improvement in the preparation process. The results show a clear difference in TATs between large specimens and small biopsies. Right now, there is an ongoing improvement concerning the efficiency of the dehydration process for large specimens, which benefits samples including breast and colon.

Use of AutoTEC embedding moulds adapted for core biopsies would streamline the embedding process, which would release staff resources to perform other tasks. Discussions should continue with the manufacturer.

One important part of lean methodology is working with small batches. Equipment that meets this demand is available on the market in some areas today, such as equipment for immunostaining. Further development of the DigiPat project is expected to lead to improved work processes which facilitate diagnostics and daily routine work.

There is much room for improvement in the histopathological process, and waste can always be found. However, it may be worth noting that even if the process were fully optimised, without any waste, TATs may still be too long due to the national shortage of histopathologists.

Implications for research
Since the time frame of this QI intervention made it impossible to study the patient's waiting time from time of surgery to start of treatment, this would be an interesting subject to study further.

The focus groups took advantage of the staff's perceptions of what it is like to work with QI interventions. The study highlights the factors that are important when working with QI interventions and shows how they can influence the outcome in a specific context. The study
does not contribute new knowledge in the form of new key factors (important when working with improvements) but nevertheless helps to improve understanding and deepen the knowledge within the field. Further research is needed that focuses on which conditions influence successful intervention outcomes and how they interact with each other.

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Appendix

1. Interview guide focus groups
2. Information about participating in the study about reducing the turnaround time in the histopathology service
3. Proportion of all reported samples within 15 days
4. Driver diagram colon resections
Appendix 1. Interview guide focus groups

**Purpose:**
Why is it important to work with improvements?

**Patients/Customers:**
What are your thoughts about the patient as a customer?
How do we identify new needs?
In what way do we work with complaints derived from customers/patients?

**People/Employees:**
What motivates you in your daily work?

**Processes:**
What do you consider to be important factors for an improvement to succeed?

**Pattern:**
What challenges can you identify when working with new procedures?
Can you identify situations when it is more difficult to follow new methods or work procedures?

**Passion/Driving forces:**
What are your driving forces?
Appendix 2. Information about participating in the study about reducing the turnaround time in the histopathology service

Background
According to the law on Swedish health care all citizens have an equal right to equal health care. The Swedish National Board of Health and Welfare’s annual report “Regional comparison”, which focuses on cancer care, highlights significant regional differences in the patients’ waiting time at different stages through the continuum of care. As an improvement measure, six regional cancer centres have been established in Sweden (RCC) in order to develop cancer care from the patient’s perspective; i.e. from the first contact to palliative care. The South-eastern Region, including Jönköping, promises treatment to residents within four weeks, which is a challenge when waits and enquiries can be both varied and unnecessarily long.

As a result of a shortage of pathologists in Sweden lasting many years, focus is often directed to the laboratory process of the treatment chain. Customers (referrals) say that the variation in report time from Clinical Pathology leads to difficulties in scheduling patient appointment times and in some cases, a time for surgery. With this background, a QI intervention was implemented during 2013 – 2015. The aims of the intervention were to:

- create an effective and streamlined turnaround time for histopathology samples
- establish agreements with customers regarding turnaround times to improve the patients’ waiting time
- visualise internal processes to increase knowledge and understanding

The purpose of the study of the intervention
The study aims to take advantage of the experience that the staff of the Department of Clinical pathology has gained from working with QI interventions. This will provide lessons for future improvements. The study will be conducted in the spring of 2015 as part of the master's work (thesis) in quality improvement and leadership, Jönköping Academy. Information obtained during the study is regulated by Swedish legislation (2009:400).

The study will include various professions working in the Department of Clinical pathology. The study is based on qualitative research, and interviews will be conducted in the form of two focus groups, with 5-6 participants on each occasion. The focus group is a form of group interview, where the conversation is focused on a specific topic, which in this case is to utilize experience that the department staff has gained from working with improvements. The interview guide will refer to the 5P; Purpose, Patients, People, Process, Pattern + Passion. The information obtained will be recorded and transcribed and will result in data which will then be analysed to study results. The group interview is expected to take approximately 1.5 to 2 hours.

Your participation in this study is completely voluntary. You may at any time terminate your participation, without giving a reason. Transcribed materials will be decoded and will not be traceable back to the individual. Sound recordings and transcribed text will be stored and archived in accordance with Swedish legislation (SFS 1990:782).

The results of the study will be available on the website of Jönköping University and will possibly be presented in a scientific journal and/or at a conference.

The study has been approved by the Ethical Committee at the School of Health Science, Jönköping University, and the reference number is 14-6. The study has also been approved by the relevant operations manager and area manager.
Informed consent to participate in the study

Reducing the turnaround time in the histopathology service - Experiences of the improvement process

I have been informed about the study and its purpose and give my consent to participate. My participation is voluntary and I may at any time and without explanation cancel my participation.

My data will be handled confidentially and kept in accordance with the practices of research ethics guidelines and good research practice. The data will be used for the evaluation of the improvement work and its outcome.

I, the undersigned, have received information about the study and hereby give my consent to participate.

City and date

Signature

Name of the signatory
Appendix 3. Proportion of all reported samples within 15 days

Both XmR charts show the same data of all samples reported within 15 days. In the chart below, a shift was inserted to highlight the novel laboratory process that started February 17th 2014 (figure 1 and 2).

Figure 1. Proportion of all analysed samples within 15 days displayed in a XmR chart.

Figure 2. Proportion of all reported samples within 15 days displayed in a XmR chart. A shift is illustrating the start of the novel laboratory process.
Appendix 4. Driver diagram colon resections

Driver diagram
colon resection

Primary impact
(2-4)
"What?"

Secondary impact
“How?"

Requests
- Number of resections
- Season
- Postal service / Electronic Data Interchange (EDI)

Time (sample)
- Preparation staff
- Diagnosis staff
- Nature of diagnosis
- Managing associated with grossing

Resources
(competencies, personnel, economy)
- Preparation staff
- Diagnosis staff
- Eliminating errors in the processes
- Developing novel laboratory processes
- Right person always doing the right things

Target/
Specific goal
All colon resections reported within 15 days
- TAT
- Distribution
**Mean TAT - colon resections**

Figure 1. Mean TAT (days) colon resections 2013 – 2014 illustrated in a XmR chart.

**Distribution measurement - colon resections (Box plot)**

Figure 2. Distribution measurement of the report time (days) 2013 – 2014 illustrated in a box plot.
Preparation time for colon resections

Figure 3. Number of days preparation time for colon resections 2013 – 2014 displayed in a XmR chart.

Diagnosis time - for colon resections

Figure 4. Number of days diagnosis time for colon resections 2013 – 2014 displayed in a XmR chart.
Resources for preparation staff (technicians)

Figure 5. Resources – hours for preparation staff (technicians) use to manage all laboratory samples 2013 – 2014 displayed in a XmR chart.

Resources for diagnosis staff (histopathologists)

Figure 6. Resources – hours that diagnosis staff (histopathologists) use to manage all laboratory samples 2013 – 2014 displayed in a XmR chart.
Number of requests for colon resections

Figure 7. Number of requests for colon resections 2013 – 2014 displayed in a XmR chart.