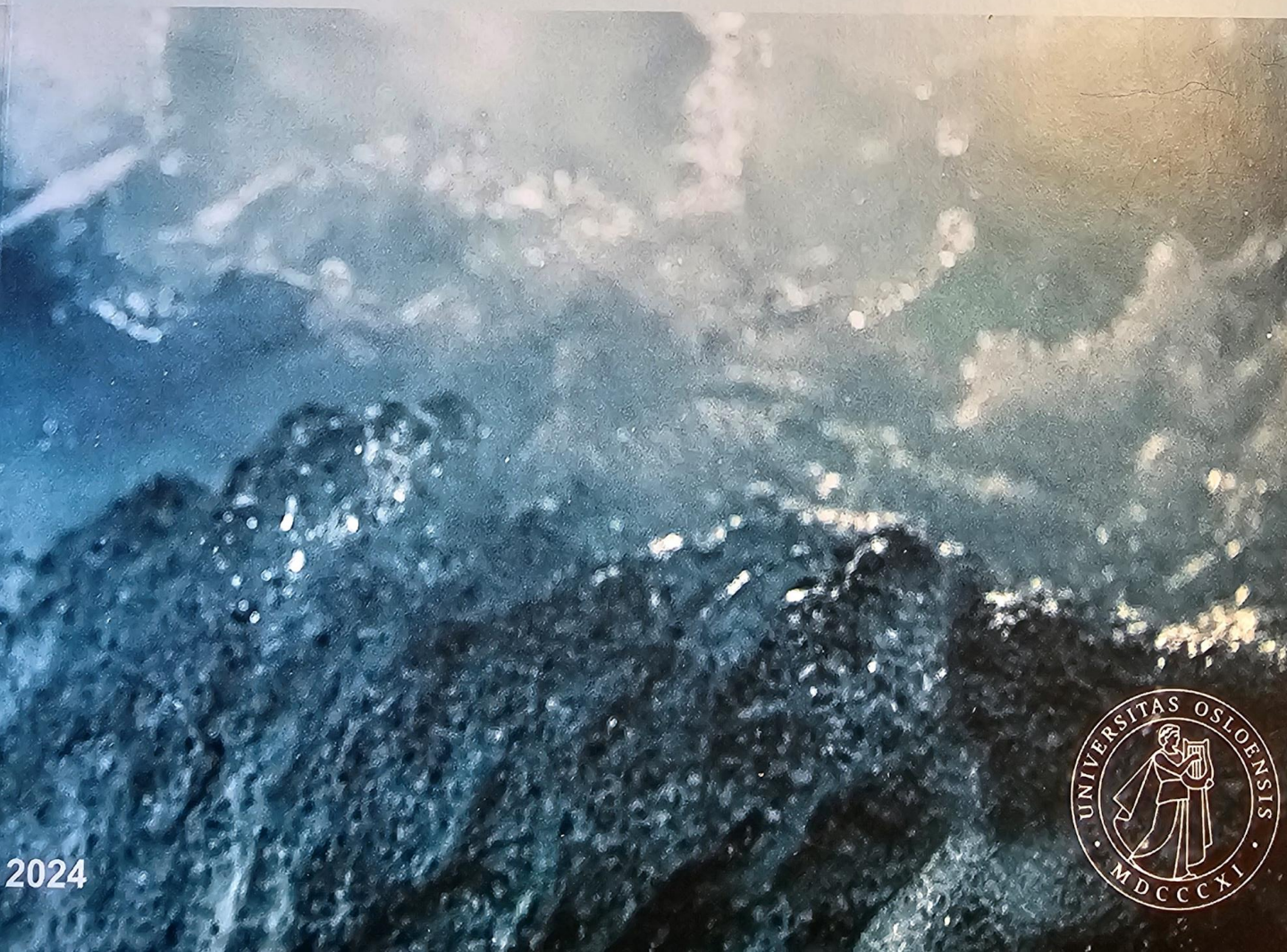
UNIVERSITY
OF OSLO

Faculty of Medicine

Tom Lian

Quality Improvement in the Treatment of Hip Fractures



2024

Contents

1. Acknowledgements

My introduction into research started with Professor Lars Engebretsen when he wanted someone to investigate the use of MRI on knee injuries in an outpatient clinic in Oslo. He wanted to copy a paper written by Frede Frihagen 10 years earlier on the same subject to see if the use of MRI had changed. Professor Engebretsen aided me in the startup and later in the writing of the article and was an inspiration throughout the process. This got me interested in research and some years later at Ringerike hospital dr. Bengt Østman kept the flame burning with his enthusiasm for science and good advice on continually keeping up to date on the newest research articles, and generally reading papers to better understand orthopedic surgery and the choices that are made.

After two years at Ringerike I got a job at Bærum hospital and met the person who would later be my supervisor throughout my PhD, dr. Wender Figved. Already an accomplished researcher and an extremely enthusiastic person, he was easy to ask when I wanted a research project of my own. Dr. Figved had started the quality improvement work, which is the basis of my thesis, some years before but was happy to have me take over parts of it to get me started. He has been a tremendous help, always available for questions and discussions. Always seeing solutions, never problems.

As part of becoming a specialist in orthopedic surgery I worked two years at Oslo University hospital. There I met my co-supervisor professor Lars Nordsletten. I think there are few single persons who have encouraged and helped so many into research. His passion for science and research is contagious and it is easy to become infected.

In the last paper of this thesis, I collaborated with a colleague from both Bærum and Oslo University Hospital dr. Svenøy. His supervisor, and our co-writer on the paper, is dr. Frede Frihagen who wrote the article my first paper was based on and so the cycle is closed.

Lastly and most importantly, I need to thank my family. My mother and father for making me the person I am today. My departed mother-in-law for always helping and being there for me and my wife, for as long as she could. And finally, I thank my wife for continuous support in all aspects of life. I would be nowhere and no one without her. She also helped create my two fantastic children, Andrea and Tomas, who both keep me striving to become a better person every day.

2. List of abbreviations

BCG	Boston Consulting Group
BSC	Breakthrough Series Collaborative
CRP	C-reactive protein
DXA	Dual-energy X-ray absorptiometry
FNF	Femoral Neck Fracture
HA	Hemiarthroplasty
HDM	Hypothetic Deductive Method
NHFR	National Hip Fracture Register
NMA	Norwegian Medical Association
OUH	Oslo University Hospital
PDSA	Plan - Do - Study - Act
SPC	Statistical Process Control
THA	Total Hip Arthroplasty
QI	Quality Improvement
XmR	Individual and moving Range

3. List of papers

Paper one

Lian T, Dybvik E, Gjertsen JE, Dale H, Westberg M, Nordsletten L, Figved W. Compliance with national guidelines for antibiotic prophylaxis in hip fracture patients: a quality assessment study of 13 329 patients in the Norwegian Hip Fracture Register. BMJ Open. 2020 May 20;10(5): e035598. doi: 10.1136/bmjopen-2019-035598. PMID: 32439694; PMCID: PMC7247399.

Paper two

Lian T, Brandrud A, Mariero L, Nordsletten L, Figved W. 60% Reduction of reoperations and complications for elderly patients with hip fracture through the implementation of a six-item improvement program. BMJ Open Qual. 2022 Jul;11(3): e001848. doi: 10.1136/bmjoq-2022-001848. PMID: 35851037; PMCID: PMC9297208.

Paper three

Svenøy S, Lian T, Figved W, Frihagen F Consequences of periprosthetic femoral fractures after hemiarthroplasty of the hip. In review.

4. Introduction

Changes are implemented in hospitals continuously. Some because of new evidence in the treatment of a disease, some for economic reasons, some for in house logistic reasons, and some just because someone thinks it is a good idea. Sadly, not all these changes are based on evidence, and even fewer are reviewed with regards to adherence and outcome after they are implemented. The science of Quality Improvement (QI) is useful for making such changes in both small and large processes safe, and at the same time, if done correctly, yield the best possible outcome of the changes.

This project saw its birth in 2013 when my supervisor started a collaboration with Boston Consulting Group (BCG). The aim of the project was to improve the treatment of all elderly hip fracture patients in Bærum hospital, by several evidence-based changes. The group brought in an expert in the field of QI in the project and worked with the changes, making them part of the daily routine of the orthopedic department. The changes were also followed and investigated by Statistical Process Control (SPC) to check for adherence at several stages.

I got involved in the project in 2016 when I wanted to investigate whether these changes led to better treatment. At the same time, I got involved in several other QI projects at Baerum Hospital. Through this I was introduced to the methods of QI research, both the statistics of SPC and the more generalized methods as described by the teachings of Walter Shewhart and his successor Arthur Deming. I attended two year-long courses during the next years and was certified as a QI-guidance counselor by Vestre Viken Hospital Trust in 2019. Because of my involvement in the field of QI it was natural for me to ask questions about other processes that were changed. One of the six processes we looked at in the original project was the correct administration of prophylactic antibiotics, as stated by the national guidelines. We saw that our hospital's compliance was good, meaning that all patients received the correct antibiotics in the correct manner. But what about the rest of the hospitals in the country? We contacted the Norwegian Hip Fracture Register for help with investigating the use of prophylactic antibiotics in hip fracture surgery around the country. The results were not what we had hoped for. It took several years after the guidelines were published before most hospitals followed them. Some hospitals have yet to adhere to the guidelines.

In our main project, we found a major reduction in complications and reoperations. But what happens when you have a complication? Dr. Svenøy and Dr. Frihagen at Oslo University Hospital were looking at periprosthetic fractures after hemiarthroplasty (HA) and wanted to describe these patients. We were contacted and asked to collaborate to better describe this complication and what impact it has on the individual patient.

5. Background

5.1 Scientific method

My PhD-thesis is, to a large degree, built on QI research, which is a completely own branch of science[1]. One of the main goals in QI research is to combine several successful and established scientific results, and then apply them to a process. The goal is that these process changes will yield a result better than the sum of the single measures. In QI research, one will typically use research results from all available research fields. In our paper on treatment of hip fractures, we used results from vastly different fields when establishing the six processes we wanted to change to best practice.

Traditionally in scientific theory, one wants to investigate structure, method, basis, and the importance of the science and the results[2]. We can divide scientific theory into two parts, descriptive and normative. Normative scientific theory describes how one should go forth to achieve progress, while descriptive scientific theory describes how the science is achieved.

When applying the methods in QI research, it is not possible to investigate causality. We want to test synergies between all our smaller processes, and whether this leads to a better outcome of our main process. We assume that causality exists based on previous research, and it is therefore important that we use established science as a base for our process changes. We hypothesize that if we change a given number of processes in a treatment process, at the same time, we will get a positive change in the overall treatment process. In scientific theory this is part of the hypothetic deductive method (HDM). We have a hypothesis, which we test, and it is then strengthened or weakened. Traditionally, HDM has been based on Karl Poppers critical rationalism[3]. The underlying process changes each have their scientific method as a base of their results.

In rationalism, one assumes that reality is available through realization and is thereby the basis of the HDM. The HDM is then based on an assumption that there is a causation. A test is developed, based on logical deduction, to evaluate a hypothesis, and then assessed for causality. In that way, the hypothesis is either verified or falsified. However, when applying the critical rationalism as described by Karl Popper, one quickly runs into the induction

problem[4]. Popper argued that it was impossible to prove general validity from single observations. He argued that there will always be other plausible hypotheses explaining the results. To solve this problem, Popper introduced a reverse burden of proof, where the goal is to falsify the hypothesis. For each time a hypothesis is falsified, the likelihood of it being false will increase, and in that way, we will gradually approach the truth.

The critical rationalism has been criticized for being too strict. For instance, it has been argued that it does not allow for shifts in paradigms as described by Kuhn[5]. Popper himself answered this by arguing that shifts in paradigms are parts of the natural scientific process, and therefore could be allowed within his framework of scientific understanding.

As part of our research, we have used results from other research groups in the introduction of orthogeriatric examination and treatment[6-10]. In our case we wanted to study treatment of hip fractures, which generally affects the geriatric population. We therefore have read, studied and applied papers having the null hypothesis that it is not beneficial to involve a geriatrician in the treatment of hip fracture patients. This null hypothesis has been falsified repeatedly, not proving, but making it probable that involvement by a geriatrician is beneficial in the treatment of hip fracture patients.

Another common scientific method we have had to rely on is the method of induction, which is based on generalizing from observations. One of the studies we used as a basis for implementing a rule of two surgeons, one being experienced, in all hip arthroplasties, used the method of induction[11]. The study found that inexperienced surgeons had more complications than experienced surgeons. We therefore deduced that by implementing a rule that at least one experienced surgeon should participate in all hip arthroplasties, we would observe fewer complications. Causality is not established here, we just assumed by deduction that there was one. There might be other reasons for why inexperienced surgeons have more complications. For instance, they usually operate more at night, while more fatigued and tired. There can also be factors outside our control influencing the results. We just do not know. Our problem is that we cannot use observations for inductive conclusions as they are not generalizable.

Lastly, all research is based in some form on the axiomatic method. It states that there are axioms that are so self-evident that they must be true and does not need to be proved. It is said that the first axiom of orthopedic surgery is that all bleeding eventually stops. One could argue whether this is a true axiom as true axioms usually goes much deeper and are more basic in our understanding of the world. Examples of well-known axioms are that "the universe is endless" or that "two plus two equals four". But axioms have fallen to scientific revolutions and shifts of paradigms throughout history, making them an uncertainty factor in all scientific research. And, because axioms are the core of all science, their fall may have ramifications far beyond the science to which they are directly connected. The most famous fall in modern history is probably when Newtonian physics fell after Einstein introduced the theory of special relativity.

"Normal science, the activity in which most scientists inevitably spend almost all their time, is predicated on the assumption that the scientific community knows what the world is like" - Thomas Kuhn

5.2 Shewhart and Deming

QI research and SPC provides the basis of this thesis but are not well known within the general medical community. Walter A. Shewhart is known as the father of SPC, which is an integral part of QI research[12]. When working at Bell Laboratories, he wanted to use sampling inspections of processes to understand them better, thereby making it possible to understand when a process was not healthy, displaying non-wanted variation, and then changing it. Shewhart introduced the control chart as a means of sampling any given process. His goal was to bring the process he wanted to understand into a state of "statistical control".

William Edwards Deming understood the enormous potential of SPC and the methodology of QI as suggested by Shewhart[13]. He introduced what he called Shewhart's cycle, now known as the Plan-Do-Study-Act (PDSA) cycle. Utilizing the techniques developed by Shewhart, Deming played an integral part in developing post-war Japan's industry. He advocated that better quality would decrease manufacturing costs as well as increasing productivity.

The teachings of Shewhart and Deming have spread to many fields outside the process industry, including medicine, during the last 50 years.

5.3 Quality Improvement research in medicine

The first papers using SPC and QI methods in a medical context were published around 1990[14]. Since then, its use has grown over the years. Today there are many specialized medical journals focusing only on quality improvement works. In the Norwegian medical community, quality improvement work formally started in 1994 after a change in the national Hospital Act demanding the creation of quality committees in all health institutions[15]. In October of 1994, all Norwegian hospitals entered into a formal agreement to further develop quality improvement work. The agreement was a success, and several joint venture quality improvement programs were established. In 1998, the Norwegian Medical Association (NMA) initiated the first Breakthrough Series Collaborative (BSC)[16]. The aim of the BSCs was to close the gap between knowledge and practice by a systematic approach utilizing quality improvement knowledge. In the following years, several BSCs were started, and today there are nine ongoing BSCs funded by the NMA[17].

In the US, the Institute of Medicine (IoM) was formed in 1970, including members not only of health care professionals but esthetics, economists, business representatives and others[18]. In 1994, the IoM released the report *America's Health in Transition: Protecting and Improving Quality*[19]. The main finding in the report is that the gap between knowledge and practice needs to be closed to assure best practice treatment. In 1999, the IoM released the report *To Err is Human*[20], in which it found that around 100.000 deaths during medical treatment in the US were caused by medical errors and thus avoidable. This attracted the attention of the public, and the Agency for Healthcare Research and Quality started a review of the quality of US health care. The discrepancy between factual treatment and recommended treatment was further described in 2001 when the IoM published the report *Crossing the Quality Chasm*[21]. The IoM has changed name to The National Academy of Medicine and is today involved in many quality improvement initiatives ever striving to breach the gap between ideal and actual treatment.

5.4 Hip fractures in the elderly

Traditionally, mortality after hip fractures has been reported to be around nine percent at 30 days and 30 percent after one year[22]. Improvements in both treatment of hip fractures and medicine in general has decreased mortality rates since this paper was published in 2005. A recent review found modern mortality rates to be around eight percent at 30 days and 22 percent at one year[23]. These numbers are comparable to our own findings[24]. 7399 hip fractures were reported to the Norwegian National Hip Fracture Register in 2020, resulting in around 1600 deaths after hip fractures in 2021 using a conservative 22 percent at one year death rate[25]. To put these numbers into perspective, pulmonary disease including Covid-19 which is the third largest cause of death in Norway took 3656 lives in 2021[26]. The underlying frailty in this patient group is negatively correlated to quality of life one year post-surgery[27]. Only 30 percent will return to pre-fracture function[28], and about one in four will need to stay in a nursing home for the rest of their life.

The true monetary cost of a hip fracture is difficult to analyze in a universally meaningful way. There are simply too many factors not comparable between countries and health systems for such analyses to be reliable. For instance, both the content and length of stay will vary between countries, as well as the level of care after dismissal from the hospital. In Norway, we have a system of universal health care providing both in-hospital care, primary physician care and aftercare in rehabilitation clinics, nursing homes and home nursing. A Norwegian report by Hektonen from 2014 did a calculation of the total cost to the Norwegian society from each hip fracture[29]. She found a mean total cost of around USD 55.500 per patient including both hospital and rehabilitation costs. Similar results were found in a Canadian study from 2013[30].

5.5 Contemporary challenges

Our main goal as medical professionals is to provide optimal care for our patients, and at the same time avoid complications. To do this we must control as many of the factors in the process as possible. To control a factor, we need to understand all its underlying processes. This process control is time consuming and not always easily available. We know that successful treatment of a hip fracture is feasible by competent surgeons using state of the art

equipment, and at the same time providing modern pre-, per- and postoperative treatment as described in several guidelines[31-34]. The treatment pathway should include involvement from the anesthesiology department, the geriatric department, physiotherapists, occupational therapists and pharmaceutical specialists as well as nursing staff during admittance, surgery and in the ward. But other parts of the hospital machine should not be forgotten. The staff responsible for cleaning, staff responsible for instrument sterility and the implant providers are also an integral part of a successful treatment pathway. After dismissal from hospital, nursing staff and doctors in the rehabilitation clinics, as well as the patients' primary physician, will play their part. It is relatively easy to control one of all the above-mentioned factors, but it becomes increasingly difficult when more factors are entered into the equation. For instance, we can control many, but probably not all, of the processes within the hospital, but we have little to no control over what happens after the patient is dismissed from the hospital in our current system.

We should have a zero-vision for human errors by providing systems focusing on the removal of errors. A relatively easy and proven system-based method to decrease errors is the implementation of checklists[35-37]. There are however challenges with checklists. They are time consuming and there are important barriers that needs to be addressed when introducing them[38-40]. Modern medicine is enormously complex, making perfect treatment every time, challenging if not impossible. We therefore need to embrace methods, like checklist, that help us in our quest for perfection.

"Clinicians now have at their disposal some six thousand drugs and four thousand medical and surgical procedures, each with different requirements, risks, and considerations. It is a lot to get right." – Atul Gawande from the Checklist Manifesto[41]

6. Aims

The main goal of this thesis is to describe QI research and how we used the QI methodology to provide better treatment for hip fracture patients. Secondarily, I also aim to describe one of the more important processes involved in hip fracture treatment, the correct administration of prophylactic antibiotics. Lastly, I explore what happens when hip fracture patents suffer a serious complication. The connection between the papers that constitute the thesis is shown below (figure 1).

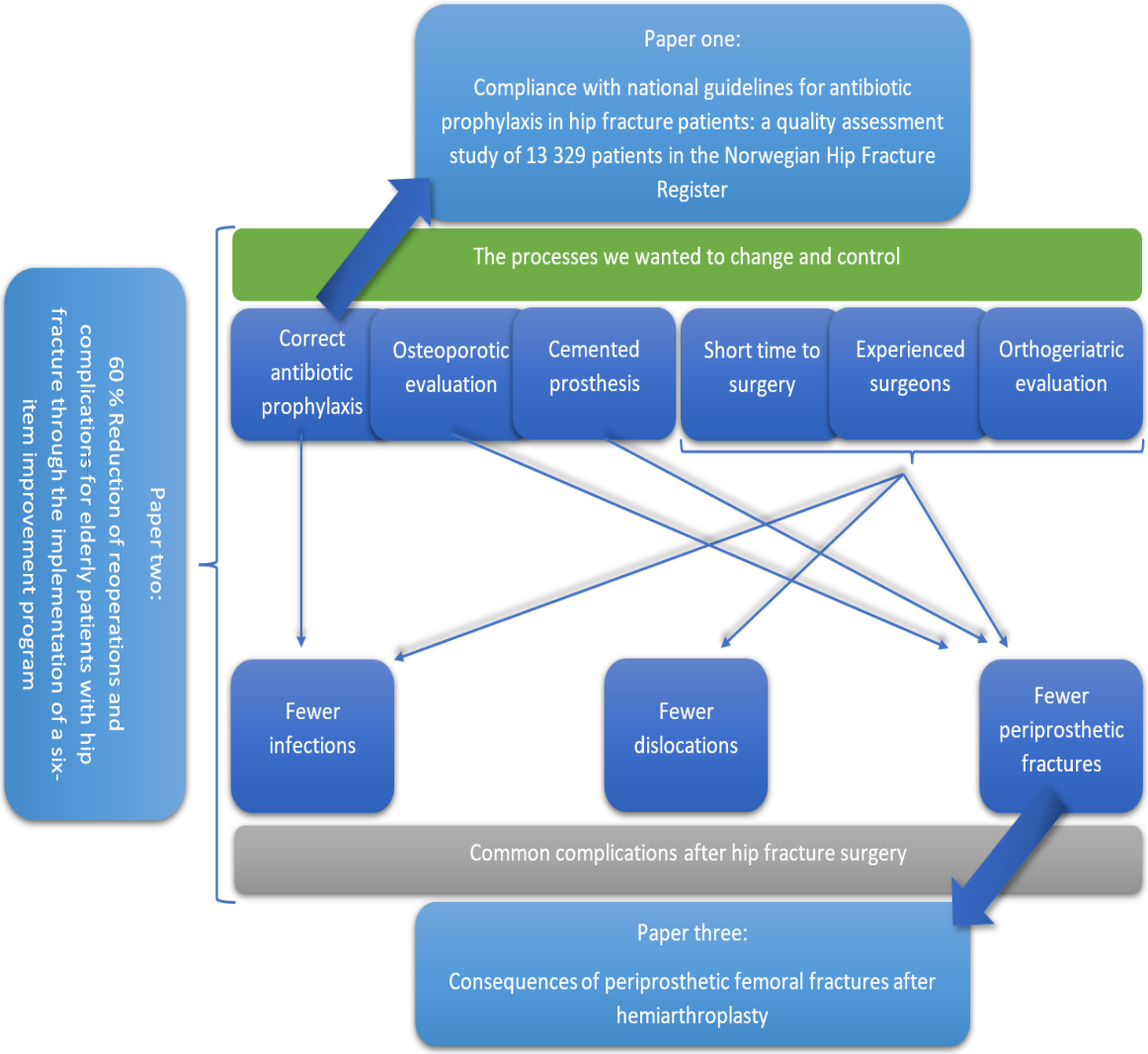


Figure 1: Overview of the thesis

7. Materials

7.1 The National Hip Fracture Register

The National Hip Fracture Register (NHFR) in Norway was established in 2005 by the Norwegian Orthopedic Association[42]. In all cases of hip fracture surgery performed in Norway a mandatory questionnaire is filled in by the surgeon post-surgery and sent to the register. At the time of our studies this was done on paper, whereas it no is done on a digital form. Currently the register contains data from 152.515 hip fractures[43]. A comprehensive coverage is essential for registers to give meaningful data and low selection bias. The last calculation in 2021 from NHFR showed a coverage of 86% for osteosynthesis and 92% for hemiarthroplasty (HA). For reoperations, the coverage was 72% after osteosynthesis and 88% after HA[25].

7.2 The hip fracture population of Bærum and Oslo University Hospital

Bærum Hospital is a local hospital in Norway providing care to approximately 190.000 inhabitants from the two municipalities Asker and Bærum[44]. Oslo University Hospital (OUH) is a hospital trust consisting of several hospitals in the Oslo area. OUH provides care to approximately 272.000 inhabitants from Oslo[44]. OUH is also a regional trauma center providing trauma treatment for the whole of the southeast of Norway. Because trauma patients are demanding with regards to resources, some patient groups, including some hip fracture patients, are treated at other Oslo-based hospitals. Both Bærum Hospital and OUH treat approximately 240 hip fracture patients per year, with 100-120 being femoral neck fractures (FNF), the rest per- and subtrochanteric fractures[25].

8. Methods

8.1 Quality Improvement

Quality is always in the eye of the beholder. For instance, quality in healthcare 100 years ago was something completely different from what we would accept today, but even by the standard of that time, we would be able to separate good from poor quality healthcare. Another example would be cultural differences when evaluating quality. A TV-program about women's rights could be considered being of good quality in some parts of the world, whereas in other parts it could be considered offensive and thus considered being of poor quality. When investigating quality in healthcare, we can examine patient outcome, but there are other important parts of healthcare quality which also could be addressed. Healthcare economics, patient experiences, health care professionals' experiences and organization are also integral parts of quality in healthcare.

In the book "Continuous Quality Improvement in Healthcare" the authors provided a framework with seven overriding factors for a successful QI program[45]:

1) Understanding and adapting to the organization's external environment.
2) Empowering clinicians and managers to analyze and improve processes.
3) Adopting a norm that customer preferences are the primary determinants of quality and that the term "customer" includes both the patient and the providers in the process.
4) Developing a multidisciplinary approach that goes beyond conventional departmental and professional lines.
5) Adopting a planned articulated philosophy of ongoing change and adaptation.
6) Setting up mechanisms to ensure implementation of best practices through planned organizational learning.
7) Providing the motivation for rational, data-based, cooperative approach to process analysis and change.

Other later authors have also found many of the same factors to be important when initiating a successful QI program in healthcare[46 47].

8.1.1 Management

The adaptation towards an environment in which QI work is a natural part of the hospital workings is essential and should be led by management[48]. Managers need to cultivate QI work by identifying possible team members to be responsible, allocate time in their work schedules and provide financial support if needed and feasible. In fact, without management involvement and/or without allocated time, it is close to impossible to perform a successful QI program[49]. Lastly, managers need to be QI champions, encouraging and supporting the team throughout the process.

8.1.2 The QI-team

There is no universally accepted method when assembling a QI-team. Some guidelines have however been published[50]. The QI program needs a leader with a superior understanding of the main process, but not necessarily with an intimate understanding of all processes within the main process. The leader also must be involved in all communication with the team, thus keeping an overview of the processes. Lastly, it is important for the leader to be a champion for the cause. The rest of the team should be comprised of personnel from several different groups, thus creating a multidisciplinary approach to the processes. A team member should be involved in an important process within the main process and have a comprehensive understanding of the process he or she is responsible for. It is advantageous if the team members and leader have previous knowledge and understanding of QI work, but lack of such could be remedied by education and guidance by QI experts throughout the process. When initiating QI-programs in healthcare it is vital to involve both patients and health care professionals when they are a part of the process we want to improve. Although preferable, neither needs to be part of the team, but they should be asked to participate with insight throughout the process.

8.1.3 Sustainability

A plan for sustainability is vital to ensure a lasting change in the processes. Implementation of change must be understood by personnel and other involved parties including management and patients. Therefore, educating and guiding of involved parties before, during and after the

changes are made is essential. Investigating outcome before and after, and then educating personnel, patients and management about the findings should always be part of the plan for sustainability. If the changes are understandable and does not involve an unreasonable increase in the workload of personnel involved in the processes and produces, a superior outcome compared to the previous treatment protocol, sustainability could and should be realistic.

8.1.4 The PDSA-cycle

Most QI programs are planned around the PDSA cycle (figure 2) of continuous improvement. The PDSA cycle is a construct often credited to Deming, but he himself referred to it as Shewhart's cycle of continuous improvement. The truth is that the cycle is much older. The first known mention of the PDSA cycle construct is from Galileo Galilei[51] and Francis Bacon[52] in the 17th century. The construct is simple, we *Plan* a change to a process, *Do* the change, *Study* the change, and then *Act* upon the findings by planning new changes if necessary. All the time working to improve the process.

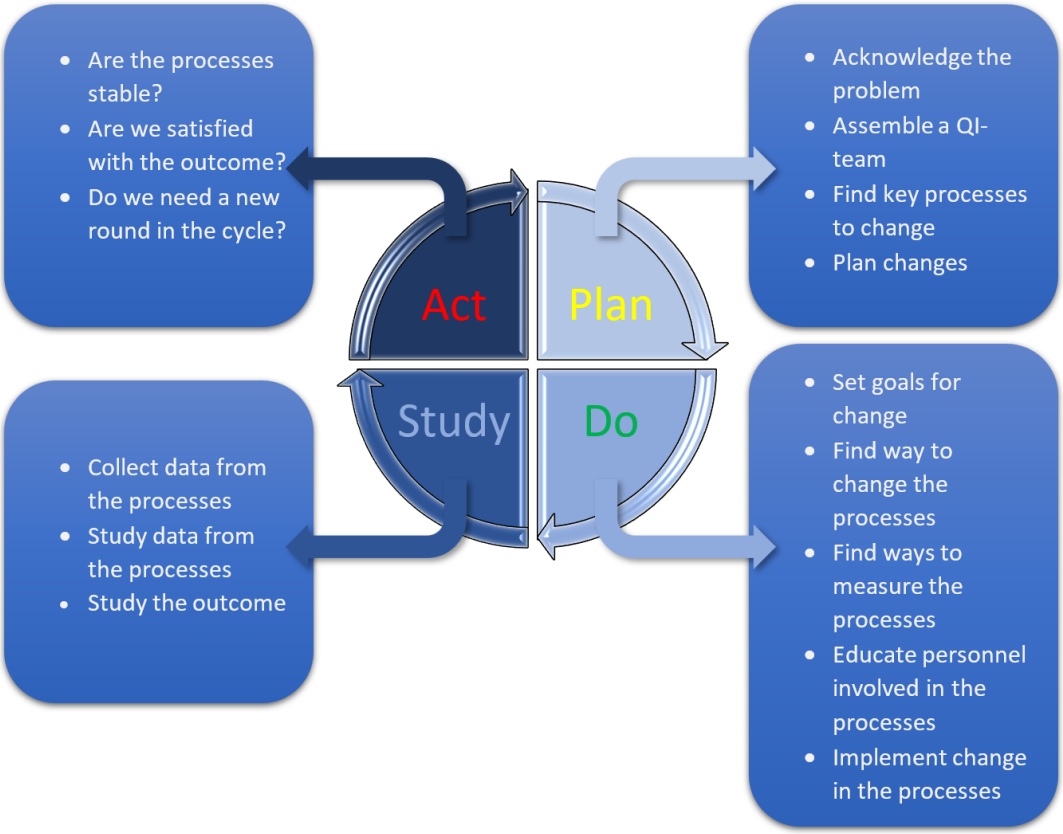


Figure 2: The Plan-Do-Study-Act (PDSA) cycle

The PDSA cycle is a powerful tool when applying careful considerations to each of the steps, but there are many pitfalls when moving through the cycle[53]. In the *Plan* phase we need anchoring in management, involved health care personnel and other stakeholders. Leadership with knowledge in management changes is essential. Barriers in the change process must be identified and dealt with, and an interdisciplinary team of interested and eager personnel from key groups must be assembled[54]. When moving over to the *Do* part of the cycle, we need to set goals for the QI program, to find ways to change the process and find ways to measure these changes. Both measurement of the actual process that is to be changed and the outcome of the changes are needed. The changes should be based on evidence from literature in the relevant field. We need to educate involved personnel explaining why the changes will likely yield a better outcome for our patients. The changes are then implemented into daily work before one can *Study* the changes. The measurements should be studied by personnel familiar with the process and with the measurement type selected for the project. We then must *Act* according to the results. The final thing to consider is if we are satisfied according to the goals set under *Do* or do we need to further improve the results?

"The definition of insanity is doing the same thing over and over again and expecting different outcomes." – Albert Einstein

8.2 Statistical Process Control (SPC)

As described in the background chapter, SPC is a form of statistical analysis developed in the 1920s by Walter Shewhart to investigate processes in real time. This means that one can, by using small samples, get an idea of how healthy a process is. The processes are categorized as stable or unstable. Within a stable process one can allow for common cause variations which are normal, have natural causes, and are to a certain degree predictable. Special cause variations on the other hand are irregular and not part of the natural process, thus yielding an unstable process. Measurements of C-reactive protein (CRP) is an example of a stable process with common cause variation when the individuals who are tested are healthy. When a patient gets an infection, the measurements are no longer stable, and we have special cause variation indicating an unstable process. What SPC does is give us a tool to identify unstable processes

before the outcome suffers. To achieve this there are several things to consider before starting the measurements. First, one must understand and know the process one wants to investigate, and all its underlying processes. The process you want to measure needs to be specific and measurable. When applied to healthcare the process you want to measure should be an integral part of the treatment, so that a change will have an impact on the outcome of the patents.

8.2.1 Charts in SPC

When conducting SPC-measurements, there are different charts to choose from. It is crucial to understand the data, to choose the appropriate chart. Carey and Lloyd[55] made a control chart decision tree which is useful in helping out with this important decision (Figure 3).

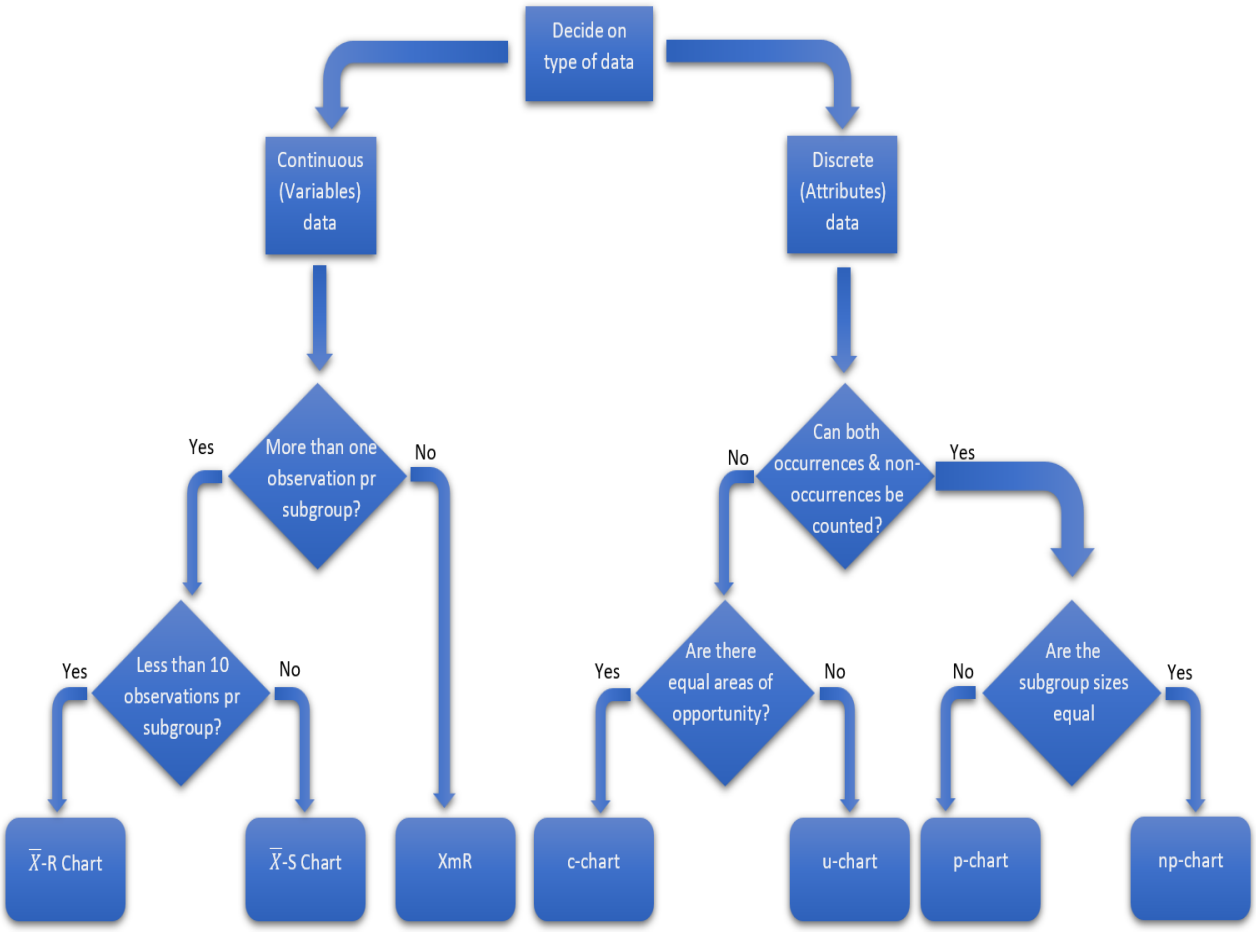


Figure 3: Decision tree for choosing correct control chart (by Carey and Lloyd)

The most basic chart is a run-diagram where you plot consecutive measurements (Figure 4). A run chart can be useful but has clear limits when we want to evaluate the process for special cause variation.

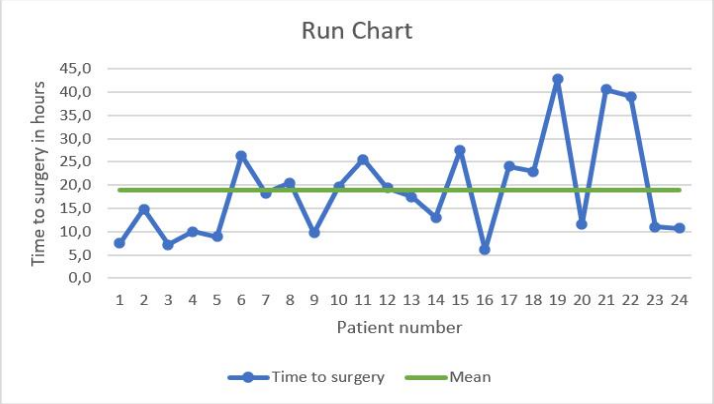


Figure 4: Example of Run Chart showing time from admittance to surgery for hip fracture patients in our material

A more useful chart when investigating our data is an individual and moving Range (XmR) chart as we have only continuous data with only one observation pr subgroup (Figure 5). We calculate an upper and lower control limit and add to our chart. The control limits are calculated by adding lines representing the mean ± 3σ, where σ represents the standard deviation of the mean.

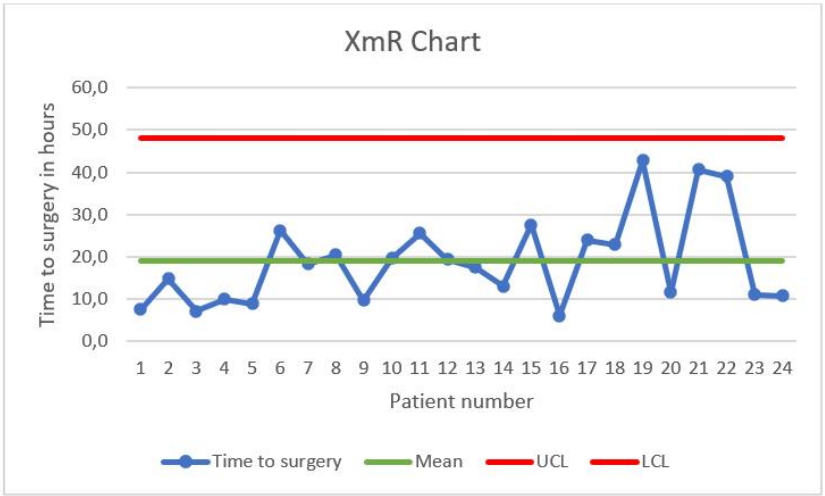


Figure 5: Example of XmR Chart showing time from admittance to surgery for hip fracture patients in our hospital with upper control limit (UCL) and lower control limit (LCL), which is below zero and therefore not shown

8.2.2 Detecting special cause variation using XmR Charts

There are five commonly used rules to detect special cause variation when examining Moving Range Charts (figure 6-10)[56].

1) If one of the measurements falls outside the 3σ lines. As a curiosity it can be mentioned that this was the only test Shewhart himself used. If the data are normally distributed the probability of this happing is 0.27 %, thus making it highly unlikely that this is a normal part of the process.

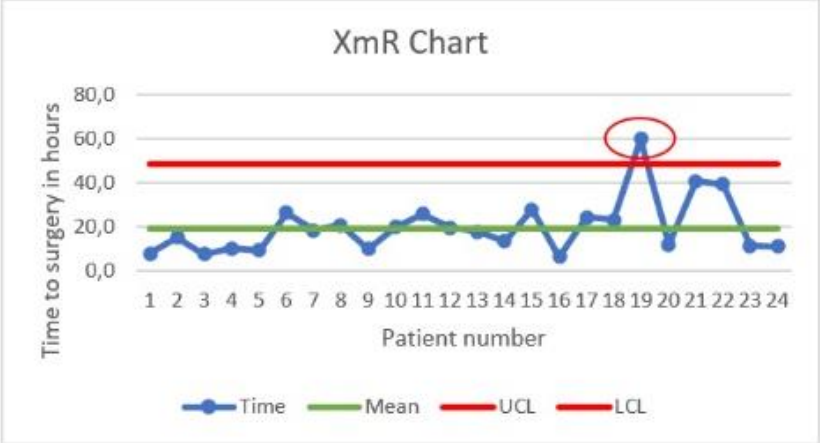


Figure 6: One point above the 3σ line

2) We have special cause variation when eight or more consecutive measurements are on one side of the central line.

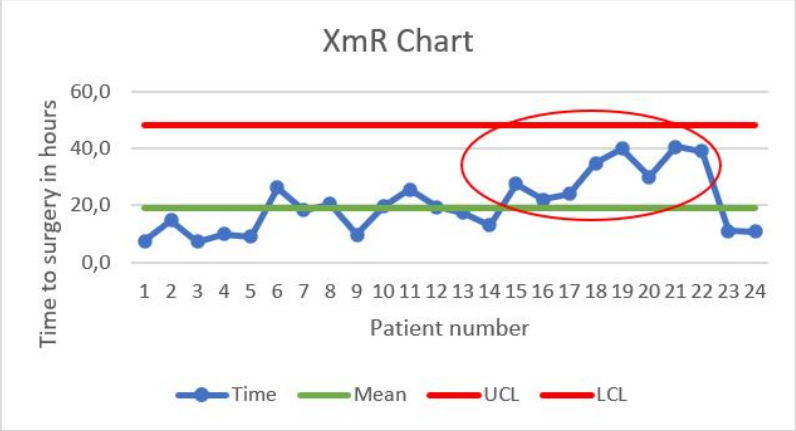


Figure 7: Eight consecutive points on one side of the central line

3) If seven consecutive measurements are either decreasing or increasing. This is called a trend.

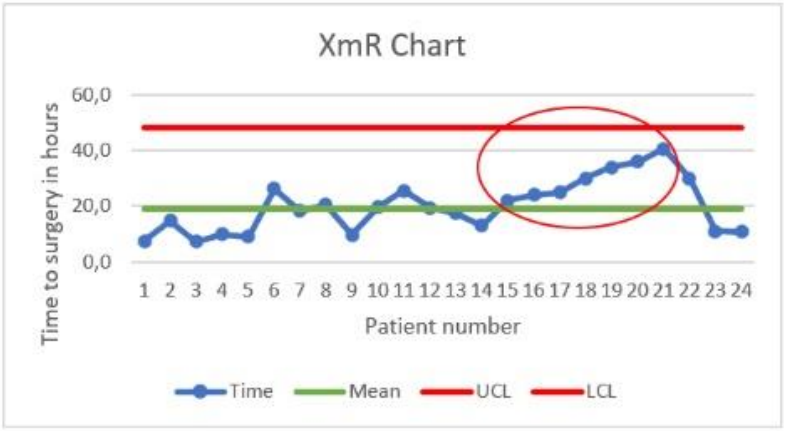


Figure 8: Trend - seven increasing points in a row

4) If two of three measurements are above or below a line 2σ from the central line.

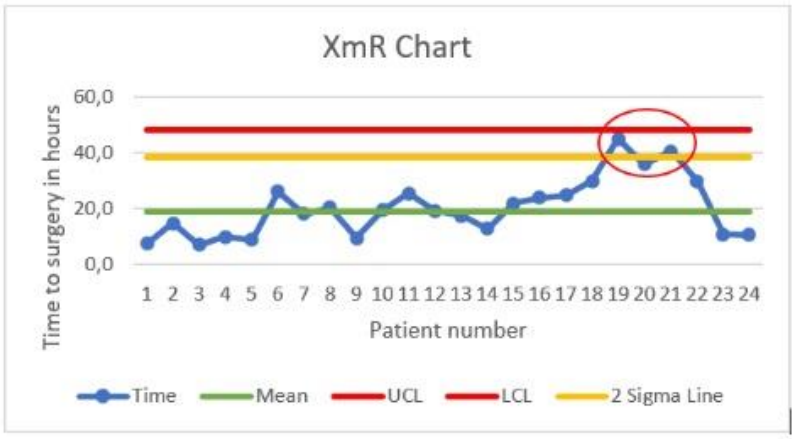


Figure 9: Two of three points in a row above the 2σ line

5) If four of five measurements are above or below a line 1σ from the central line and on one side of the centerline.

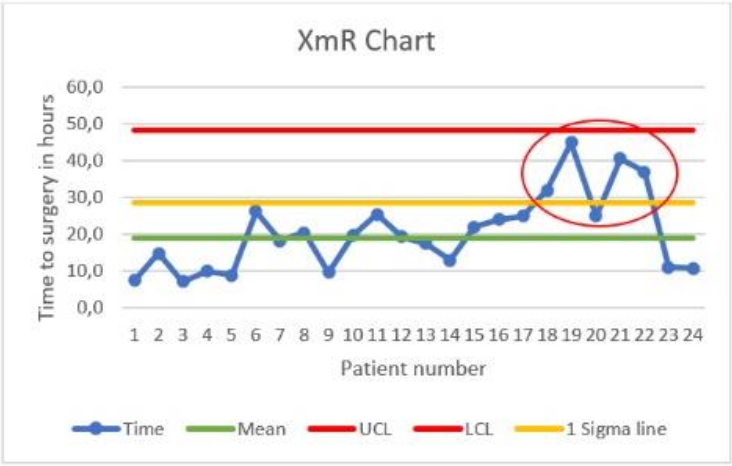


Figure 10: Four of five points in a row above the 1σ line

When one of the five above mentioned test are positive, we need to consider our data and processes. Is it possible that we have a change in the mean (change in level)? Are there other possible explanations? If, for instance, we have a trend (seven points in a row with increasing/decreasing value) after a change in the process, we should evaluate this new process in a new time series with measurements. If, on the other hand, if we have one point above the 3σ line, we must look at that point. Did something special happen? To understand a special cause variation, we need to have a comprehensive understanding of the process and its underlying processes.

8.3 Comparison of groups

In paper two, we checked for normality but could also assume normality because of the central limit theorem with our 475 observations, and then used t-test for comparison of group characteristics. All calculations of t-tests were performed with Stata SE 17. Defining the null hypothesis, that the groups were different, we found no differences in patient characteristics with all p-values well above 0.05. When comparing the groups, with the same null hypothesis, regarding complications and reoperations we found differences with p-values below 0.05. Because we also wanted a time-to-event analyses we used Cox-regression and thereby Hazard

Ratio finding significant differences at the 5% level between the groups regarding complications and reoperations, but not regarding death.

8.3.1 Understanding the p-value and significance

The p-value is telling us that there is a chance equal to (1-p-value)×100, under the null hypothesis, that our observations are true. The British statistician Ronald Fisher is credited with having described a p-value of 0.05 as a "threshold for significance"[57]. It sems he chose the number arbitrarily , but other contemporary statisticians were also working with the same number[58]. There are also those arguing that 0.05, or 1/20, is a natural, universally understandable significance level[59], but it should be remembered that nothing magical happens when the p-value moves marginally beneath the 0.05 threshold. The p-value must be interpreted in the context of the null hypotheses and the research methodology you are using. The use of the term "statistical significance" should be used with care, if at all. The American Statistical Association stated in 2014 in *The American Statistician* that

"*Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold",*

and were in general skeptical to the use of the term "statistical significance" in scientific publications[60].

8.4 The National Hip Fracture Register

All statistics in paper one was performed by statistician Eva Dybvik from the NHFR. The analyses were performed using IBM-SPSS, version 24.0 (IBM Corp., Armonk, NY, USA) and the statistical package R, version 3.4.0 (R Development Core Team, Vienna, Austria). We compared means of groups using ANOVA, but none of these computations made it to the final paper. Other than ANOVA we mainly looked at change over time using graphs and percentage at certain point to compare the different hospitals. All statistics and graphs in paper two was conducted using GraphPad Prism version 9 for Mac (GraphPad Software, Insight Partners, New York, NY, USA).

9. Summary and results

9.1 Paper one

In Paper one, we focused on the implementation of and adherence to national guidelines for prophylactic antibiotics in Norway, specifically for hip fracture patients. The guidelines were first introduced in 2013, and they recommended two specific antibiotics. The timing between doses of the antibiotics and number of doses recommended were also parts of the guidelines. When guidelines are introduced, we need to know if they are being followed. This is an important part of the PDSA-cycle. First, we plan the guidelines (Plan), then we introduce them (Do). Then we need to investigate (Study) whether the guidelines are being followed, and act accordingly (Act). We cooperated with the NHFR studying all patients from a time reaching three years before to three years after the guidelines were published and found 13,329 patients eligible for inclusion in the analyses. We looked at adherence to the guidelines over time comparing all hospitals, and then specifically university hospitals compared to both each other and to all hospitals. Almost all hospitals quickly achieved adherence to the guidelines with regards to type of antibiotic. When investigating the transition to correct administration (number of doses and timing between), as recommended by the guidelines, we found a slow but steady improvement from 2013 to 2016. University hospitals were quicker at adapting to the new guidelines, but at the end of the study period only 60% of prophylactic antibiotics for hip fracture surgery were administrated as recommended in the guidelines in Norway. We argued that modern medicine is far too complex not to rely on evidence-based guidelines, and that the issue of noncompliance should be addressed. Real time measurements of the process of prophylactic antibiotics, using checklists and SPC, could be a good instrument for correcting the process. We also argue that local leadership should be involved and held accountable if guidelines are consistently not followed. In the end, all health care treatment in Norway is the responsibility of the National Directorate of Health, and it should be in their interest that guidelines in well-studied fields of medicine are followed. The paper was written using the STROBE-guidelines as a framework[61].

9.2 Paper two

Paper two is the largest part of this thesis. The project started in 2013 and was concluded in 2021 when sustainability, with a clear improvement in outcome, was found. We wanted to improve the treatment of all hip fracture patients by finding the processes with the biggest impact on the outcome and changing them to best practice. We sought help from both local and external personnel familiar with QI work. Their advice led us to examine all available literature, interview key personnel and do a thorough chart review to better understand the processes involved in the treatment of our hip fracture patients. We found six processes that we concluded were the most important to quality assure (figure 11). Prophylactic antibiotics have a major impact on infection risk and is the single most important prophylactic measure against surgical site infections[62-64]. For hip fractures treated with arthroplasty, reports of infection rates vary from 2% to 17%[65]. Early surgery (< 36 to 48 hours) is a key element in most guidelines and have shown reduced mortality for geriatric patients with hip fractures[66 67]. Experienced surgeons, proven implants, and the use of bone cement in arthroplasty treatment in the elderly, have shown reduced reoperation rates[11 68-72]. Comprehensive geriatric care (CGA) improves outcomes for frail older patients[7 8]. A major concern in postoperative treatment of hip fracture patients is development of delirium, as it is a known risk factor for falls[73]. There are several known risk factors for development of delirium such as pain, lack of mobilization, dehydration, infection and polypharmacy[74 75 76]. Interventions from the orthogeriatric team optimized the medical and pain treatment, ensured early mobilization and implemented hygienic measures reducing the fall risk and thus of periprosthetic fracture, deep infection and dislocations. After orthogeriatric care was introduced in the UK, the mortality among hip fracture patients decreased[9 10] . Strong evidence supports the use of an interdisciplinary care program for patients with hip fractures[6 7 10]. Orthogeriatric care is performed by an interdisciplinary team of professionals specialized in treatment of elderly patients, usually comprised of a geriatrician, an orthopedic surgeon, a nursing staff trained in geriatrics, physiotherapists, occupational therapists, clinical pharmacologists, and in some cases a nutritionist and a social worker. For secondary fracture prevention, a Fracture Liaison Service (FLS) aiming to identify and treat patients with a fragility fracture, employs a dedicated coordinator to act as the link between the patient and the orthopedic team and the primary care system[77 78]. For hip fracture patients, Zoledronic acid 5 mg intravenously along

with vitamin D and calcium supplements, have shown a substantial lowered risk of a subsequent fracture[79-81].

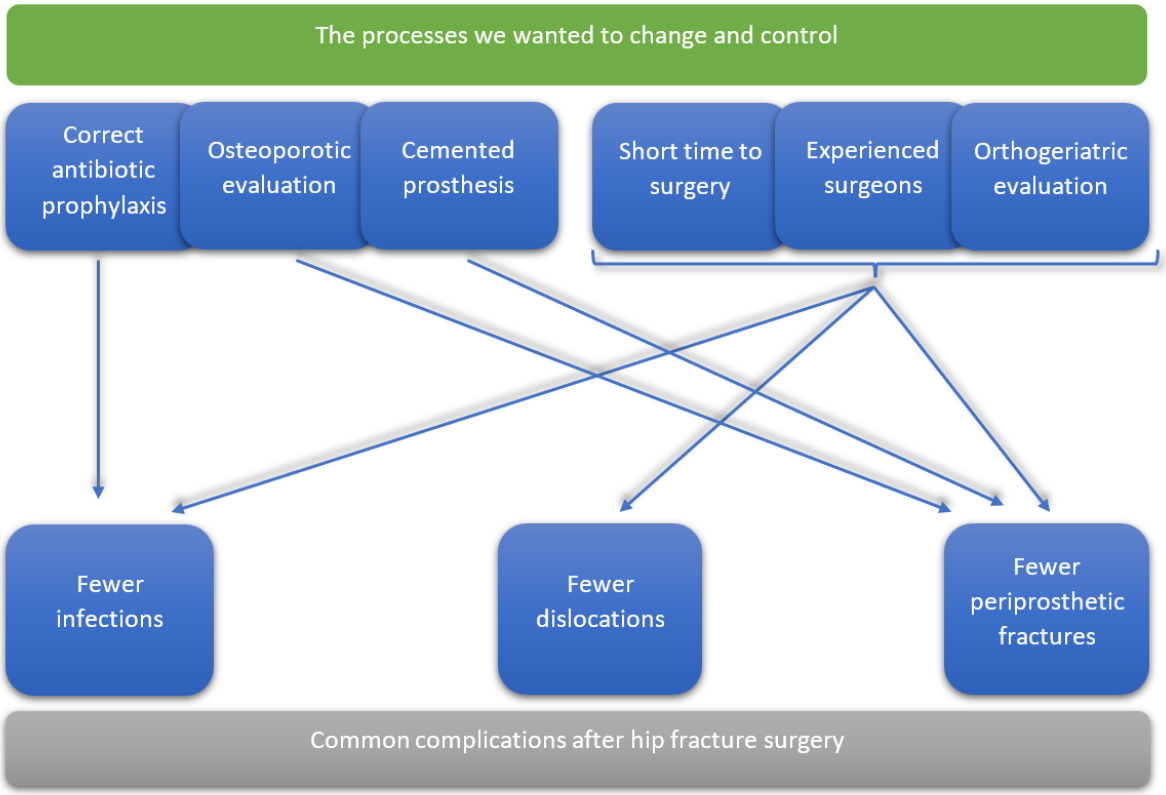


Figure 11: The six processes we found most important to change and investigate

Our chart review had shown that two of the six processes, correct antibiotic administration and less than 36 hours from admittance to surgery, were already in place. The change to two surgeons only meant a minor increase in the workload of the consultants and was quickly adopted. The change of prosthesis type needed a more planned approach, with education of surgeons and operating nurses before the change was both safe and possible. Orthogeriatric and secondary fracture prevention evaluations were more challenging to implement. Both came at a monetary cost, and local management had to be educated and then persuaded to budget for these new processes. We needed to hire a geriatrician, an occupational therapist, and implement our already existing clinical pharmacist for our comprehensive orthogeriatric evaluation. For secondary fracture prevention, we introduced a department wide rule of initiating treatment as if the patient had established osteoporosis for all hip fracture patients.

By the end of 2015 we had purchased a dual-energy X-ray absorptiometry (DXA) and could start a full Fracture Liaison Service[82].

It was important for us that the changes should be measurable, while at the same time allow for individual evaluation of every patient. We developed a checklist for the purpose of evaluation and investigated our adherence before the project, and then three times during the first year, each time making small changes to our processes where we found low adherence. Parallel to this we worked non-stop with education of both management and all personnel involved in hip fracture treatment, explaining why the changes were necessary. After the first year we had almost full compliance with the desired treatment processes. We then performed three more investigations in the following year showing sustainability of the changes. When we were satisfied with the sustainability of the changes, we started investigating outcome differences before and after all changes were implemented. We found a 60% reduction in both complications and reoperations after all desired changes were in place. For this fragile patient group this could yield a tremendous increase in their overall quality of care. Finally, we did an additional measurement of sustainability in 2021, seven years after the changes were first introduced, showing still adherence above 90%. We then concluded that the new processes clearly remain a part of the daily routine of our department, and thus sustainability had been achieved. The paper was, as recommended in all QI-work, written using the SQUIRE-guidelines as a framework[83].

As an addendum it should be mentioned that three of our six changes now are part of the four quality indicators monitored by the NHFR. The indicators are correct antibiotic prophylaxis, short time to surgery and cemented arthroplasty as well as arthroplasty for displaced femoral neck fractures. The last indicator was already part of our treatment algorithm, whereas the first three were part of the study.

9.3 Paper three

In Paper three, we looked at the consequences of sustaining a periprosthetic fracture after HA for FNF. Although we could only find 56 patients over a 10-year period, no previous work has been published describing these patients and their outcome. We found an increase in dependency in 17 of 56 patients after the periprosthetic fracture. 34 patients needed a

permanent place in a nursing home after whereas 22 needed it before the periprosthetic fracture. We could not find a difference in the mortality rate when comparing to primary HA for FNF. We concluded that the new fracture was comparable to a regular FNF with regards to death risk but led to an increase in dependency and thus decrease in mobility and likely quality of life.

10. Discussion

10.1 The advantage of following the processes in real time

The main advantages of using SPC is its ability to follow processes in real time. Changes to a process can be monitored and evaluated continuously, thereby making it possible to intervene if the process is unstable and thereby yields an unstable outcome. What we want is a stable process that gives us a predictable result. An unstable process has special cause variation which we need to investigate. There can be external factors influencing the process which are found to be extremely rare, and thereby not possible to control. But there can also be special cause variation that we need to address and try to remove. When applying this technique, we gradually decrease the special cause variation and thereby make the process more and more stable thus attaining a predictable outcome from the process. When applying the PDSA-cycle to a problem we can make changes to the process to hopefully get an even better outcome. We then need to evaluate the new processes and again investigate and remove special cause variation continuously working towards a stable process with a perfect outcome.

10.2 Considerations when changing several processes at the same time

The main advantage of changing several processes at the same time is that if chosen correctly, the processes will have a synergistic effect on each other thus awarding us with an outcome that is better than the sum of its parts. The weakness of changes several processes at the same time is that it is impossible to find which single process had the largest impact on the new outcome. It might be that one of the processes has no, or even a negative, impact. When choosing processes to change and how to change them, it is imperative that the changes are based on evidence-based findings and chosen by personnel with an intimate understanding of the main process. This to minimize the risk of introducing changes that have a negative impact on the outcome.

10.3 Considerations when using SPC

We know that a stable process will produce a predictable outcome. Therefore, when achieving a stable process, it is easy to become complacent, but a predicable outcome is not the same as

an optimal outcome. It is crucial to evaluate the processes constantly for possible improvements. New scientific findings should be assessed continually for incorporation or a complete change in the processes. The search for improvement within our processes must be continuous and never-ending.

An issue we need to be aware of is when a change within a process, that does not yield a change in the SPC-data, occurs. An example of this can be found in our own data. The year after data for our second paper was collected, we were forced to change our femoral stem for HAs due to a large tender-based purchase conducted by the regional health authorities. After this change of prosthesis, we know we had a significant increase in complications reported to the NHFR. This continued until the health authorities cancelled the contract and introduced a choice of four different prostheses (hospitals could choose one out of four alternatives), with numbers of complications dropping again. All three prosthesis types, the one used in the study, the second with many complications and the third we now use were cemented, and thus gave us good compliance scores when looking only at the SPC-data. In retrospect, we realize that we should have continued following the processes for outcome after changing it. Changes in processes should always be evaluated both for stability and outcome.

10.4 Strengths and weaknesses of using register data

When studying a large population using register-based data, there are some inherent strengths and weaknesses[84]. Drawing certain causal conclusions from register data is not possible. The most common way to adapt to this problem is utilizing the contrafactual framework. If we for example want to assess the effect of four doses of antibiotics, we have to compare it against the effect of fewer doses in the same patient. This is of course not possible, and we run into the fundamental causal interference problem. To work around this issue, we make control groups with patients with similar characteristic, but who receives fewer than four doses and compare those to the ones receiving four doses. For this method to be feasible we must consider selection bias in the register and must explore confounding, interacting and colliding factors in a thorough way.

A high number of procedures included and that nationwide results are presented are both strengths in using register data. Most weaknesses are connected to the questionnaire, missingness and the completeness of the register. The data are always limited by the questions

and registrations on the operation form filled in by the surgeons. There is also a possibility that the way in which the questionnaire is filled may be different from the surgeon records and what actually happened. For example, Stefánsdóttir et al[85] showed in 2009 that although recommendations for timing of the preoperative antibiotic infusion were known, only 51% of the patients received it correctly in her study. There are numerous explanations for this, one being that the questionnaires were filled in incorrectly thus corrupting the register data.

Missingness in register data needs to be studied carefully. There are several statistical approaches to consider depending on the type of missing data you have. And it is essential to choose the correct method depending on your findings in your study of the missing data.

10.5 Strengths and weaknesses of retrospective studies

One of the major strengths of a retrospective study is that it represents the real world with unselected patients. Large prospective studies are extremely resource- and time consuming to manage, whereas large retrospective studies are usually easy to deal with thus making it possible to include many patients. The weakness most often mentioned when discussing retrospective studies is missing data[86]. Since there is no control of the data possible to accumulate, there will always be missing data. If this missing data is important for the study, it can make the statistics difficult or in worst case useless. There will always be questions about the validity of the findings, since chart reviews or register data are uncertain with regards to accuracy by the one filling in the chart or form. It is in some cases possible to work around this uncertainty by utilizing statistical methods, but not always and not with 100% certainty[87].

10.6 Following guidelines

To minimize variation the Norwegian Health Directorate has published several guidelines for treatments in Norwegian hospitals, one of them being for prophylactic antibiotics in orthopedic surgery[88]. There was in our findings an increase in compliance with the guidelines for prophylactic antibiotics in orthopedic surgery in Norway. This led us to conclude that the national guidelines were gradually being implemented in Norwegian hospitals. There was not, however, as one would have hoped for, a sharp increase in correct use of antibiotic after the introduction of the guidelines. We are not anywhere near the goal of 100 % compliance

throughout Norway. This needs to be addressed, both when evaluating existing guidelines and when planning new guidelines. If guidelines are well rooted in evidence, there are few, if any, reasons not to follow them. The question is why some hospitals were, and still are, so slow at adapting these new guidelines. We suggest several reasons for this:

1) Information was not readily available.

2) The Norwegian Directorate of Health was not good enough at spreading the information.

3) Orthopedic surgeons and their leaders were not willing to change their practice.

The answer is probably a combination of the three. Spreading the information and making it available should be primarily The National Health Directorates responsibility. There is also a clear responsibility for local leaders to follow up on guidelines and regulations from the national health authorities and inform and educate their staff about them. The problem of surgeons and leaders not following regulations and guidelines made by national health authorities is more challenging to solve. Some surgeons and leaders are fast adapters and willing to change, whereas others are more conservative. To remedy this, we need strong leadership and incentives for change. The cost of this is less autonomy which may be a feared development in some environments, but eminence-based medicine has no place in modern medicine, for that it is far too complex.

«To believe without evidence and demonstration is an act of ignorance and folly.”- Socrates

11. Conclusions

This PhD consists of three papers on the treatment of hip fractures. The focus has been on continuous improvement. In the first paper, we concentrated on how prophylactic antibiotics were administered in the treatment of hip fractures in Norway. We saw a need for an evaluation of this process of antibiotic administration, as the Norwegian recommendations were not being followed to a satisfying degree. In the second paper I participated in and investigated the outcome of a quality improvement project on the treatment of hip fractures. We found a remarkable decrease in complications and reoperations after a change in six important processes around the treatment of hip fractures. In the last paper, we investigated a population of periprosthetic hip fractures after HA for a hip fracture. This population has, to our knowledge, not earlier been investigated in a thorough way. We found no evidence of an increase in risk of death when comparing to primary surgery for FNF with HA, but a clear increase in dependency thus indicating a decrease in mobility and likely in quality of life.

12. Future research

12.1 Finding the best antibiotic prophylactic regime

There is a large body of evidence pointing towards prophylactic antibiotics as the most important factor in the fight against postoperative infections[62 63 89-98]. However, several topics remain controversial. To find the universally best antibiotic regime is almost impossible. There are simply too many factors to consider. First, one must choose the correct drug. An important factor to consider is that the drug should be both effective against the local bacterial flora, but at the same time not resistance-driving. Local bacterial flora will vary from country to country, thus making a universal choice impossible[99]. The second thing to consider is the administration, both dose and timing of the doses. We know that a high enough dose should be available in the local tissue when the operation starts, but we have no means to easily measure the local concentration of antibiotics. We have an idea of what the concentration should be in healthy tissue, but when investigating hip fractures, we are dealing with compromised blood circulation and thus compromised delivery of antibiotics. We do not know for certain how many doses should be administered and in what dose. One study has shown that four doses are preferable to one, two or three [96]. On the other hand, some authors argue that the dose given before surgery is the most important[64 89]. For the antibiotic to have an effect, it is important that the concentration does not drop below a certain threshold. This threshold is known for most antibiotics, but not the local concentration in damaged tissue. It is important to understand that recommendations for prophylactic antibiotic type needs to be tailored to local conditions. In most cases, country wise choices for antibiotic type should be possible. The timing and dose of the antibiotic, as well as how many doses are administered, needs be further researched.

True penicillin-allergy is rare, but adverse effects such as urticaria, pruritus and nausea are common[100]. These effects are commonly misinterpreted as true allergy, and broader spectrum antibiotics are frequently chosen as prophylaxis. It has earlier been estimated that there is up to 10% cross-sensitivity between penicillin and first generation cephalosporins. This has, however, been refuted in later years[101]. According to one review, the risk of an anaphylactic reaction is increased by a factor of four when the patient has had an earlier serious reaction to penicillin[102]. The percentage of patients with a true allergy is not known. Studies have

estimated the number at 1-5 per 10,000 cases[100], but this will probably vary between different genetic makeups[103] and is therefore difficult to assess. It is challenging in a clinical setting to be certain about what earlier adverse reactions represent, and testing for antibiotic allergy is not readily available in orthopedic departments, thus some overuse of broader-spectrum antibiotics may therefore be acceptable. There should however be a greater focus on finding methods for identifying patients with true allergic reactions, thereby reducing the unwanted use of any broad-spectrum antibiotics.

12.2 Finding the best type of orthogeriatric care

There are many forms of orthogeriatric care described in the literature[104-107]. It is not possible to research and describe optimal care in a meaningful way because of local differences. It should however be possible to research and provide a framework for possible local adaptations. The types of recourses for orthogeriatric care to have a positive impact on the overall treatment process is also possible to research and describe. It is imperative to understand that orthogeriatric care is multidisciplinary teamwork[108]. Therefore, the impact of each process could and should be researched, but at the same time understanding that the goal is achieving a result larger than the sum of its parts.

12.3 Finding the optimal prosthesis

There is more and more evidence towards choosing a cemented prosthesis when dealing with frail and elderly patients with femoral neck fractures[72 109-112]. There is however no clear-cut definition of frail and elderly that will help us with the choice of implant. In the last 10-15 years hemi-arthroplasty has been the favored treatment, but there are those who argue that a total-arthroplasty could be a better choice for some patients[113-116]. There is consensus that joint preserving procedures with an osteosynthesis of some kind is better for the young. But who is young? If you have an elderly and frail patient hemi-arthroplasty is probably the best choice, but where does the cut-off go? Who would benefit from a total hip arthroplasty (THA) and who might profit from an osteosynthesis? It is unlikely that we will find a universally true answer for all patients to these questions, but it is reasonable to believe that individual and evidence-based tailoring should be possible in the future.

Another unanswered question regarding prosthesis choice is design. There are many designs and design categories[117 118]. One study found that polished tapered femoral stems had lower revision rates when compared to cementless designs in THA, while a Norwegian register study found that straight and anatomical prosthesis had a lower risk of revision than tapered stems in HA[119]. While this could lead to us to believe that a straight or anatomical stem should be the prosthesis of choice in HA, there are still many prosthesis designs not thoroughly investigated.

12.4 Finding the optimal approach

There are several approaches available when doing hip arthroplasty, whether it be total or hemi, each with clear and mostly known pros and cons. Some authors have argued that a lateral approach is superior to the posterior approach due to higher risk of dislocation in the posterior approach[120-122]. However, others claim that the posterior approach is superior due to the risk of Trendelenburg gait in the lateral approach[123 124]. To try and remedy the increased risk of dislocations with a posterior approach a new technique, Saving Piriformis And Internus, Repair of Externus (SPAIRE), has been developed and has shown promise[125]. The SPAIRE technique has not been fully investigated, and conclusions are not possible to draw so far. There are also those who champion the anterior approach as the approach of choice. The superiority of the anterior approach has yet to be found in any study[126 127], and has to my knowledge not been studied in femoral neck fractures.

12.5 Finding the optimal treatment protocol for hip fractures

The optimal treatment protocol for hip fractures is composed of many factors. In our research, we have implemented and investigated six factors we found important. There are however many factors that are yet to be researched. We had a goal of short time from admittance to surgery but did not investigate what should happen in this period. What is optimal preoperative care? Perioperatively there are also many processes not investigated in our material. The best antiseptic technique, best surgical approach, best femoral stem, best pre-, per- and postoperative anesthesia are only some of the factors still debated. Concerning postoperative care, we had several important factors in place, but no control with what

happened after the patient left the hospital. Optimal aftercare after dismissal from the hospital, with all processes involved, has not been studied comprehensively and will need further investigation.

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14. Papers

BMJ Open

Compliance with national guidelines for antibiotic prophylaxis in hip fracture patients: a quality assessment study of 13 329 patients in the Norwegian Hip Fracture Register

Tom Lian ,[1] Eva Dybvik,[2,3] Jan-Erik Gjertsen,[2,3,4] Håvard Dale,[3,4,5] Marianne Westberg,[6] Lars Nordsletten,[6,7] Wender Figved[1]

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For numbered affiliations see end of article.

Correspondence to
Dr Tom Lian;
tom.t.lian@gmail.com

ABSTRACT

Objective We assessed compliance with new guidelines for prophylactic antibiotics in hip fracture surgery in Norway introduced in 2013.

Design The data from the Norwegian Hip Fracture Register was used to assess the proportion of antibiotics given according to the national guidelines.

Setting All hospitals in Norway performing hip fracture surgery in the period from 2011 to 2016.

Participants We studied 13 329 hemiarthroplasties (HAs) for acute hip fracture.

Main outcome measure Type and timing between first and last dose of prophylactic antibiotics compared with the national guidelines.

Results Before the guidelines were introduced, the recommended drugs cephalotin or clindamycin was used in only 86.2% of all HAs. In 2016, one of the two recommended drugs was administered in 99.2% of HAs. However, hospitals' adaption of the recommended administration of the two drugs improved slowly, and by the end of the study period, only three out of five HAs were performed with the correct drug administered in the correct manner. We found major differences in compliance between hospitals.

Conclusions The change towards correct administration of antibiotic prophylaxis was varied both when investigating university and non-university hospitals. We suggest that both hospital leaders and the national Directorate of Health need to investigate routines for better dissemination of information and education to involved parties. Strong leadership concerning evidence-based guidelines on antibiotic prophylaxis in surgery may take away some autonomy from executing healthcare professionals, but will result in better patient care and antibiotic stewardship.

Strengths and limitations of this study

- The strengths of our study are the high coverage and completeness of the Norwegian Hip Fracture Register combined with the large number of patient forms we were able to investigate.
- Another strength is that the forms are filled out by the surgeon immediately after surgery, thereby ensuring correct information regarding prophylaxis.
- One limitation of our study is the lack of clear guidelines for clindamycin as a prophylactic drug.
- There may be a discrepancy between what was filled in on the form and the actual timing of the prophylaxis.
- The last clear limitation is the high number of excluded cases.

INTRODUCTION

Due to the complexity of modern medicine, guidelines and checklists have become a necessary part of treatment in all medical fields. For guidelines and checklists to have effect, it is imperative that they are used and followed. Until 2013, there were no national guidelines for prophylactic antibiotics in orthopaedic surgery in Norway, and many different regimens were used. Engesaeter *et al*[1] found the lowest risk of revision, for any reason, if four doses of antibiotics were administered systemically on the day of surgery in total hip arthroplasty. Extended prophylaxis of 2 or 3 days did not decrease the revision risk compared with four doses administered on the day of surgery according to that study.

Guidelines for prophylactic antibiotics in orthopaedic surgery was first introduced in Norway in 2013.[2] The guidelines were based on a thorough evaluation of available knowledge, using the Grades of Recommendation Assessment, Development and Evaluation (GRADE) system[3] as a tool for giving the best possible recommendations and were published on the Norwegian Directorate of Health's website.[2] The guidelines state that cephalotin, a first-generation cephalosporin, should be the only drug of choice, except in

cases of penicillin allergy, where clindamycin should be used instead.

Cephalotin has a half-life of about 45 min, and should, therefore, be administered at short intervals (the guidelines state an interval of 90 min), to exceed minimal inhibitory concentrations (MIC). It is also recommended that the first dose should be administered 30–60 min before the incision is made.[4–7] Studies have shown that this first dose probably is the most important one.[6 8] For arthroplasty procedures, four doses were recommended. In cases of known penicillin allergy, four doses of clindamycin, administered every 6 hours, were recommended. When the guidelines were published, the aim was to improve administration of prophylactic antibiotics. From many different administration regimens, to a uniform regimen throughout Norway.

The aim of this study was to assess whether hospitals in Norway follow the new guidelines published by the Norwegian Directorate of Health, and if so, at what pace the guidelines were implemented.

MATERIAL AND METHODS

The Norwegian Hip Fracture Register (NHFR) has collected data on all hip fracture procedures in Norway since 2005.[9] The information about the patient, fracture and type of surgery, as well as type of antibiotic prophylaxis, number of doses and duration recorded as the time interval between the first and the last dose in hours is reported to the NHFR on a one-page questionnaire completed by the surgeon immediately after each surgery. The questionnaires are sent from each hospital to the NHFR database for registration. Both primary surgery and reoperations are registered. The completeness of reporting to the NHFR compared with the Norwegian Patient Registry has been found to be 94.5% for primary hemiarthroplasties (HAs).[10]

The data from 19 106 HAs due to femoral neck fracture registered in the NHFR from 1 January 2011 to 31 December 2016 were evaluated, spanning 2 years before and 4 years after publication of the new guidelines. In this studied period, around 90% of femoral neck fracture patients in Norway were treated with HA.[10] Of these, some HAs had incomplete information on the total number of antibiotic doses (2521), type of antibiotic drug (107) and duration of prophylaxis (2805), and were excluded. We also excluded HAs where patients received more than one drug for prophylaxis (344). This left 13 329 HAs eligible for analyses.

One large hospital had a high number of excluded patients (n=1128). From that specific hospital, only 323 cases had been correctly reported, representing an inclusion rate of only 22%. Therefore, this hospital was excluded from the analyses due to infrequent correct reporting. Excluding the remaining reported cases from that hospital did not change our findings. In comparison, 27 hospitals had an inclusion rate of more than 75% and only 9 had an inclusion rate of between 50% and 60%.

Analyses of number of doses and duration of cephalotin prophylaxis revealed four main groups: completion of four doses within 4.5, 6, 12 and 24 hours, respectively. The timing of the first dose is not recorded in the NHFR, meaning that verification of whether this dose was given before surgery or not was not possible. We could, however, verify that doses were given at intervals short enough to keep concentrations above MIC. Stipulating that both 4.5 and 6 hours could be interpreted as correct administration of four doses with intervals of 90 min, we decided to treat these as one group, leaving three groups for analyses: in the first group, completion of all doses was registered as administered during the first 6 hours postoperatively; in the second group, it was completed between 7 and 12 hours postoperatively and in the third group, between 13 and 24 hours postoperatively. Four doses of cephalotin administered during the first 6 hours postoperatively were defined as the correct administration according to the guidelines.

The first version of the guidelines did not contain recommendations on number of doses or dosage for clindamycin. Therefore, both three and four doses of

Table 1 Type of antibiotic prophylaxis used from 2011 to 2016

	2011	2012	2013	2014	2015	2016
Cephalotin total	1860 (82.6%)	1926 (90.0%)	1919 (93.1%)	2070 (95.0%)	2109 (95.2%)	2346 (94.8%)
Correct administration (%)			86 (4.5%)	406 (19.6%)	955 (45.3%)	1379 (58.8%)
Incorrect administration (%)			1833 (95.5%)	1664 (80.4%)	1154 (54.7%)	967 (41.2%)
Clindamycin total	82 (3.6%)	73 (3.4%)	86 (4.2%)	86 (3.9%)	97 (4.4%)	112 (4.5%)
Correct administration (%)			74 (86%)	72 (83.7%)	83 (85.6%)	100 (89.3%)
Incorrect administration (%)			12 (14%)	14 (16.3%)	14 (14.4%)	12 (10.7%)
Other drug	311 (13.8%)	142 (6.6%)	57 (2.7%)	24 (1.1%)	9 (0.4%)	16 (0.6%)
Total	2253	2141	2062	2180	2215	2474
Correct administration (%)			7.8%	21.9%	46.9%	59.8%

Table 2 Patient characteristics

	Correct antibiotic and administration as stated in the guidelines of 2013	Incorrect antibiotic or administration as stated in the guidelines of 2013	All groups
Total number of HAs	3316	10013	13329
Age, mean	82.9	82.5	82.6
Gender, male (%)	1010 (30.5)	3020 (30.2)	4030 (30.2)
Dementia, no (%)	2047 (61.7)	6352 (63.4)	8399 (63)
Dementia, yes (%)	901 (27.2)	2564 (25.6)	3465 (26)
Dementia, uncertain (%)	306 (9.2)	908 (9.1)	1214 (9.1)
Dementia, missing (%)	62 (1.9)	189 (1.9)	251 (1.9)
ASA 1 (%)	29 (0.9)	122 (1.2)	151 (1.1)
ASA 2 (%)	997 (30.1)	3258 (32.5)	4255 (31.9)
ASA 3 (%)	1998 (60.3)	5872 (58.6)	7870 (59)
ASA 4 (%)	261 (7.9)	661 (6.6)	922 (6.9)
ASA 5 (%)	2 (0.1)	9 (0.1)	11 (0.1)
Missing ASA (%)	29 (0.9)	91 (0.9)	120 (120)
Anterolateral approach (%)	183 (5.5)	741 (7.4)	924 (6.9)
Direct lateral approach (%)	2466 (74.4)	8271 (82.6)	10737 (80.6)
Posterior approach (%)	634 (19.1)	811 (8.1)	1445 (10.6)
Other/missing approach (%)	33 (1)	190 (1.9)	223 (1.7)

clindamycin given over a period of 8–24 hours were defined as the correct administration according to the guidelines.

Treatments for all types of hip fractures are included in the NHFR. HAs account for approximately 34% of the total number of registered operations. More than 90% of the displaced femoral neck fractures in patients older than 70 years are treated with an HA, so the included operations make up the vast majority of the surgeries for these fractures. We did not include hip fractures treated with any form of osteosynthesis, as the recommendations in the guidelines are prophylaxis during surgery, and not after as is the case with HAs. Most HAs are performed by junior registrars, whereas total hip arthroplasties are performed by consultants specialising in hip surgery. We, therefore, excluded hip fractures treated with total hip arthroplasty to remove bias from more experienced surgeons.

We analysed 6 university hospitals and 44 non-university hospitals in Norway reporting to the NHFR. When

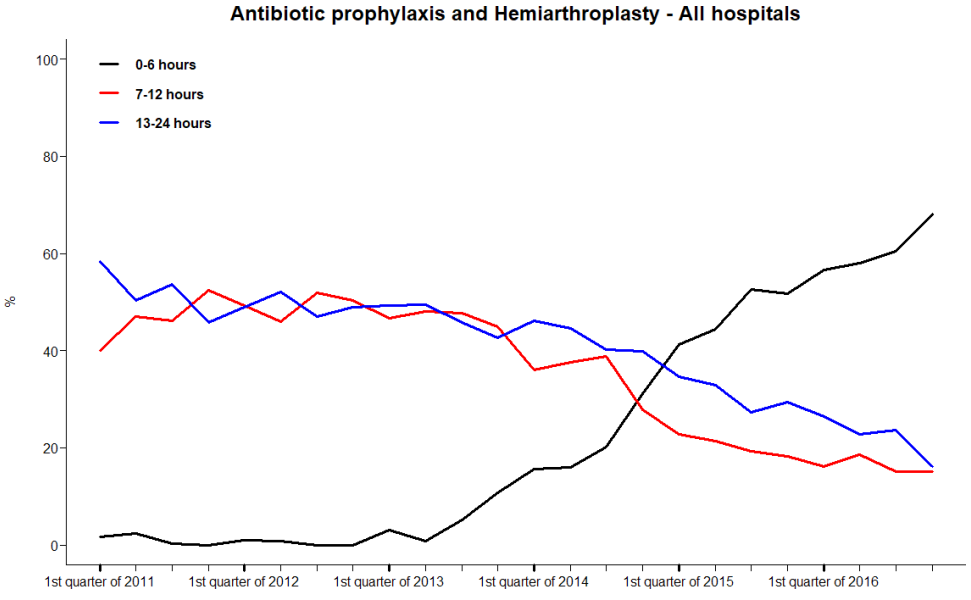

Figure 1 Antibiotic prophylaxis and hemiarthroplasty—all hospitals.

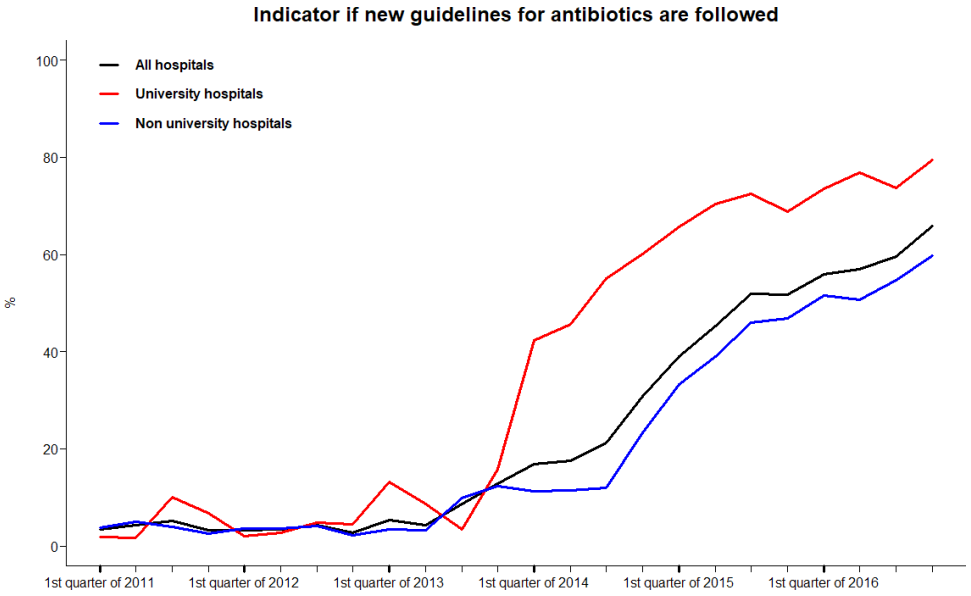

Figure 2 Indicator if new guidelines for antibiotics are followed—all hospitals.

cephalotin or clindamycin was used, we recorded whether it was administered correctly, and if there were any changes in their use from 2011 to 2016. We also assessed compliance, defined as 100% correct administration as described in the guidelines.

Descriptive statistics

The quarterly compliance with the national guidelines during 2011–2016 was calculated both for university hospitals and non-university hospitals. One university hospital submitted a high number of incomplete forms to the NHFR during the whole study period, and was consequently excluded from the comparisons of university hospitals. Analyses were performed using IBM SPSS, V.24.0 (IBM Corp.) and the statistical package R V.3.4.0 (http://www.R-project.org).

Patients and public involvement

This research was conducted without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

The NHFR has permission from the Norwegian Data Protection Authority to collect and store data on hip fracture treatment (permission granted on 3 January 2005: reference number 2004/1658–2 SVE/–). The patients have signed a written, informed consent, and in case they were not able to sign, their next of kin could sign the consent form on their behalf. This study only used data registered in the NHFR and no interventions were

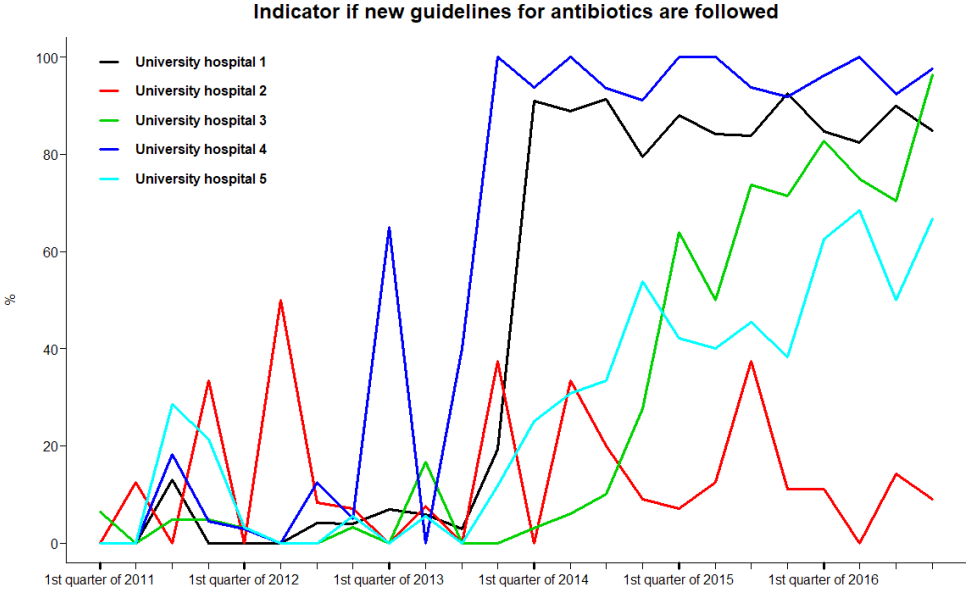

Figure 3 Indicator if new guidelines for antibiotics are followed—university hospitals.

done. The study was, therefore, performed in accordance with the regulations from the Norwegian Data Protection Authority and no ethics approval was necessary.

RESULTS

Types of antibiotics used 2011–2016

In 2011, 99.6%[11] of HAs received intravenous antibiotic prophylaxis, but cephalotin or clindamycin was used in only 86.2% of all HAs. This number rose steadily throughout the study period: in 2016, one of the two recommended drugs was administered in 99.2% of HAs. There was a small increase in the use of clindamycin during the period, whereas other antibiotics were gradually abandoned (table 1).

Compliance with the national guidelines

Table 2 shows baseline data for the 13 329 HAs included in the compliance analyses, dividing antibiotic prophylaxis according to the guidelines and other regimens. The groups were similar in age, gender, American Society of Anesthesiologists (ASA) class and cognitive function. HAs performed with a posterior approach were more often performed with the correct prophylactic regime compared with other surgical approaches. 10.8% of HAs in the study period were performed using a posterior approach. In 2011, only 4% of the HAs were performed with antibiotic prophylaxis as later recommended in the guidelines of 2013. We found a small but marked change towards administration of all four doses of cephalotin within 6 hours during 2014 (figure 1). However, for clindamycin, no such trend was found. Although better than cephalotin, erronous administration remained at 10%–15% for the whole study period. This meant that only 21.9% of HAs received antibiotic prophylaxis in concordance with the guidelines in 2014.

The proportion of patients receiving correct administration of cephalotin increased steadily after 2014 and towards the end of the study period. In 2016, almost 60% of all registered HAs were performed with prophylaxis as recommended in the guidelines (figure 2). There were major differences between hospitals. Some hospitals showed a rapid change of practice shortly after the guidelines had been published, whereas others had yet to comply with the guidelines by the end of 2016. Two of the five university hospitals changed their routines according to the guidelines during the first months after they were published, two gradually became compliant and one did not comply at all (figure 3). University hospitals adapted to the new guidelines faster than non-university hospitals. There was, however, a similar rise in correct administration in both hospital categories (figure 2).

DISCUSSION

The change towards correct administration of antibiotic prophylaxis in HAs for hip fracture was slow after introduction of the national guidelines. At the end of the study period, only three out of five HAs were performed with the correct drug administered in the correct manner. Most university hospitals adapted to the new guidelines faster than non-university hospital, but one university hospital did not comply with the guidelines at all.

From a quality control perspective, any contemplated changes to a process must be thoroughly evaluated to fully assess their impact. This is a part of Shewhart's four-part cycle of *Plan, Do, Study* and *Act*,[12] and an essential part in improving the quality of any process. When the new guidelines were published, it was after an extensive evaluation (*Plan*). The introduction was performed by distributing the new guidelines by email and with lectures held around the country and publication on the National Directorate of Health webpage (*Do*). We now need to evaluate whether hospitals follow the new guidelines, and whether following the guidelines has any effect on infection rates (*Study*). If Norwegian hospitals do not follow the guidelines, we need to understand why, and if there are differences in antibiotic regimes that lead to differences in infection rates, we then need to act (*Act*).

Prophylactic antibiotics are known to have a major impact on infection risk.[8] It is the single most important prophylactic measure against surgical site infections.[13–16] We found a gradual increase in adherence to the Norwegian guidelines published in 2013. Recommendations on time between doses were slowly implemented, and at the end of the study period, still less than 60% of the HAs were performed with antibiotic prophylaxis according to the guidelines. University hospitals were faster at adapting the new guidelines than non-university hospitals.

Several studies have reported on adherence to guidelines with regards to surgical antibiotic prophylaxis,[17–21] with varying results. A Dutch study[22] showed that guidelines can be effective in improving the process of care, but that there are large differences in the impact of each guideline. When evaluating the influence of a guideline, the first and most important factor to examine is whether the guidelines actually are being followed. If guidelines are not being followed, we need to understand why. Grimshaw and Russell[23] suggested a classification for probability of success when implementing new guidelines, where local education of clinicians was the most important factor. He also advocated rigorous evaluation of existing guidelines. Cabana *et al*[24] gave seven reasons for why clinicians do not follow practical guidelines. All these barriers can, in our opinion, be overcome by strong leadership and education of the health practitioners.

There is clear evidence that checklists may have a positive impact on results.[25–28] A study from 2011 concluded that leaders are a key factor in the implementation and further utilisation of checklists.[29] Another tool that is available is a statistical process control (SPC).[30] This has been used for monitoring processes in real time in the process industry for many years and is gradually becoming a part of research into quality of healthcare.

Type of drug

Cephalotin is not the most potent antibiotic against postoperative infections. But, when considering antibiotic stewardship and common bacteria causing postoperative infections, it has been considered the best choice for antibiotic prophylaxis in HAs in Norway. A more broad-spectrum antibiotic prophylaxis will probably yield fewer postoperative infections, but would at the same time be ecologically unwanted.

In our study population, cephalotin and clindamycin were already the two most commonly used prophylactic antibiotics in HA surgery before the guidelines were published. There was an increase in use of these antibiotics during the study period, reaching almost complete adherence in choice of drug with the guidelines. There may always be indications for using other antibiotics, such as concomitant medical conditions. We, therefore, conclude that, when it comes to the type of antibiotic, Norwegian orthopaedic surgeons are adherent to today's guidelines.

Timing

Correct timing of antibiotics, defined as the recorded time interval in hours between first and last doses, should ensure that the concentration of antibiotics in the tissue stays above MIC at all times. With the short half-life of cephalotin, this can only be achieved by short intervals between doses.

In our study, two out of five HAs were performed with cephalotin prophylaxis using intervals exceeding 90 min, 4 years after the introduction of the guidelines. Given today's guidelines, and understanding of how prophylactic antibiotics work, deviance from them is unrecommendable. Less than 60% adherence to the national guidelines 4 years after the introduction of new guidelines may necessitate an intervention by local hospital leaders as well as the Norwegian Directorate of Health.

Differences between hospitals

University hospitals should be at the forefront of change, and up to date on current knowledge. It is problematic that one university hospital did not comply with the obligation of reporting to the quality register (NHFR). This ought to be corrected (*Act*). It is also noticeable that one of the six university hospitals did not comply with the guidelines. In our opinion, there is no excuse for such oversight, and it should be remedied. Again, local leaders need to be involved, if not the National Directorate of Health may have to intervene. In Norway, each hospital generally uses one surgical approach and one standard prophylaxis for HAs. It is rare, if not non-existent, to find one hospital using several different approaches or allowing the administration of different antibiotic prophylaxis on a surgeon-by-surgeon basis. This may explain the difference we found when comparing surgical approaches. One of the few hospitals using the posterior approach was almost 100% adherent to the guidelines, thus giving this difference.

Strengths/weaknesses

The high number of procedures included and that nationwide results are presented are both strengths in the present study. When studying a large population using register-based data, there are some inherent weaknesses.[31] Most are connected to the questionnaire and the completeness of the registry. The coverage in the NHFR is 100% and the completeness is 94.5% for HAs.[10] This high completeness in the NHFR yields a low selection bias and a high external validity of our results. Our data are limited by the questions and registrations on the operation form filled in by the surgeons. There is a possibility that the antibiotic prophylaxis actually given may be different from what the surgeon records. For example, Stefánsdóttir *et al*[32] showed in 2009 that although recommendations for timing of the preoperative antibiotic infusion were known, only 51% of the patients received it correctly. However, we have no reason to expect a systematically incorrect reporting from the surgeons. The timing of the first dose of antibiotic prophylaxis is not reported to the NHFR. This information would have strengthened our study on adherence to the national guidelines, but would have been even more important in a study investigating the benefit of correct antibiotic. The lack of clear guidelines for clindamycin when the guidelines were published is problematic when interpreting the results. However, we argue that allowing for the use of either two sets of guidelines available in the period removes some of the problem. That being said, we recognise this as problematic.

A high number of cases were excluded due to incomplete information on the operation forms. The excluded cases demonstrated similar baseline characteristics as the included patients (for all variables presented in table 2). They were excluded during the whole period we investigated (between 13% and 18% each year). Furthermore, except for one hospital, the excluded cases had been reported fairly evenly from all hospitals. A more complete registration would have increased the number of cases investigated, and accordingly strengthened our results. We do not know for sure whether the excluded cases represent a systematic reporting of incomplete data, or represent a random selection of cases which probably have had antibiotic prophylaxis according to the hospital's routine at the time of operation. However, we do know that this incomplete reporting comes from most of the reporting hospitals during the whole period investigated. There is, therefore, a reason to believe that most excluded patients had received either correct or wrong antibiotic prophylaxis. We, therefore, believe that the included cases make up a representative selection and can still be used to investigate compliance with guidelines at Norwegian hospitals, but we also acknowledge that the missing cases represent a weakness of our study.

CONCLUSION

The national guidelines have gradually become implemented at Norwegian hospitals. A rapid increase in

correct use of antibiotic immediately after the introduction of the guidelines was only found in a few hospitals. Throughout the country, hospitals still fail to comply with the guidelines. This must be addressed, both when evaluating existing guidelines as well as when planning new guidelines. As long as guidelines are based in evidence, there are few, if any, reasons not to follow them.

By using checklists and combining them with the SPC data, it should be possible to follow processes and intervene when they are not stable. No single hospital in our study showed 100% adherence to the guidelines. This shows that there still exist individual surgeons not adherent to hospital policy and the national guidelines. Early identification of non-compliance needs be brought to the attention of local leaders. If this does not lead to change, the National Directorate of Health and the public should be notified.

Modern medicine is complex and dependent on compliance to evidence-based guidelines. Eminence-based medicine may still be warranted in some areas, but in fields where there are evidence-based guidelines it has no place. To conclude, we advocate more guidelines in complex and well-studied fields in medicine and strong adherence to existing ones.

Author affiliations
[1]Orthopaedic Department, Baerum Hospital, Vestre Viken Hospital Trust, Gjettum, Norway
[2]Norwegian Hip Fracture Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
[3]Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
[4]Department of Clinical Medicine, University of Bergen, Bergen, Norway
[5]Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
[6]Division of Orthopaedic Surgery, Oslo University Hospital, Oslo, Norway
[7]Institute of Clinical Medicine, University of Oslo, Oslo, Norway

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ORCID iD

Tom Lian http://orcid.org/0000-0003-0087-5598

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60% Reduction of reoperations and complications for elderly patients with hip fracture through the implementation of a six-item improvement programme

Tom Lian ,[1,2] Aleidis Brandrud ,[3] Lars Mariero,[4] Lars Nordsletten,[2,5] Wender Figved[1,2]

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[1]Orthopedic Surgery, Bærum Hospital, Vestre Viken Hospital Trust, Drammen, Norway
[2]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway
[3]Department of Research and Innovation, Vestre Viken Hospital Trust, Drammen, Norway
[4]Oslo Office, Boston Consulting Group, Oslo, Norway
[5]Orthopedic Surgery, Oslo University Hospital, Oslo, Norway

Correspondence to
Dr Tom Lian;
tom.t.lian@gmail.com

ABSTRACT

Introduction Hip fractures are common, serious and costly fractures in the elderly population. Several guidelines seeking to ensure best practice have been introduced. Although our institution complied with national guidelines for early surgery of hip fractures, no assessment of other evidence-based measures existed. We wanted to assess, test, implement and measure the impact of a quality improvement (QI) programme consisting of key elements proven to be important in the treatment of hip fractures.

Methods We formed a multidisciplinary QI team, consisting of several specialists in different fields. The QI team assessed multiple possible process measures for inclusion in the programme and selected six measurable interventions for implementation: early surgery, correct administration of prophylactic antibiotics, surgery using proven methods and expertise, a multidisciplinary patient pathway and secondary fracture prevention. The improvement process was monitored by a statistical process control chart (SPC). Complications, reoperations and mortality were compared before (n=293) and after (n=182) the intervention.

Results The SPC analyses indicated increasing adherence with all interventions throughout the improvement programme, and sustainability 7 years later. The last four periods showed a stable adherence above 90%. We found 60% reduction in major complications after the implementation of the improvement programme, from 19.1% to 7.7% (HR: 0.38 (95% CI: 0.23 to 0.61, p=0.0007). The need for reoperations due to complications fell from 12.6% to 4.9% (HR: 0.37 (95% CI: 0.21 to 0.67, p=0.0054). We did not find a difference in post-operative mortality after the implementation of the QI programme (HR: 0.95 (95% CI: 0.74 to 1.2, p=0.645).

Conclusion Our multiprofessional improvement programme achieved almost full adherence within 2 years and was sustainable 7 years later. The quality and safety of the care process were improved and led to a substantial and sustainable decrease in complications and reoperations.

INTRODUCTION

Hip fractures are common, serious and costly fractures in the elderly population, and the global prevalence is expected to increase to about 4.5 million in 2050.[1] Because of the scale and the seriousness of the problem, several guidelines for treatment of hip fractures aiming to ensure best practice have been introduced.[2–6] We know that prophylactic antibiotics administered correctly have a major impact on infection risk, and is the single most important measure against surgical site infections.[7–9] Early surgery (<36 to 48 hours from hospital admission) is another key element in most guidelines, and is shown to reduce mortality for geriatric patients with hip fractures.[10 11] Other elements in most guidelines are experienced surgeons (three or more years of experience), proven implants, and the use of bone cement in arthroplasty treatment in the elderly, which all have shown reduced reoperation rates.[12–17] Comprehensive geriatric care (CGA) improves outcomes for frail older patients[18 19] and after orthogeriatric care was introduced in the UK, the mortality among hip fracture patients has decreased.[20 21] Strong evidence supports use of an interdisciplinary care programme for patients with hip fractures.[19 20 22] Orthogeriatric care teams are comprised of a team of professionals specialised in treatment of elderly patients. The composition of the team may vary, but usually contains a geriatrician, an orthopaedic surgeon, a nursing staff trained in geriatrics, physiotherapists, occupational therapists, clinical pharmacologists, and in some cases a nutritionist and a social worker.

For secondary fracture prevention, a Fracture Liaison Service (FLS)[23] aiming to identify and treat patients with a fragility fracture, and acting as the link between the patient, the orthopaedic team and the primary care system, is recommened.[24 25]

Adherence with evidence-based guidelines is likely to reduce complications and the need for reoperations, as well as decrease

postoperative mortality rates. However, adherence with guidelines varies, representing unwarranted variation in treatment with increased risk of poor outcomes.[16 26–28] The challenge is to standardise when possible, without removing the complexity of each patient from the process.[29] To prevent undesired variation, some countries measure and publish national quality indicators and outcomes from hospitals as an incentive to increase adherence to their national guidelines.[30 31]

Our hospital is a general hospital in Norway for a local population of approximately 200 000 inhabitants, and the only hospital in this area with an emergency ward. Prior to the intervention, the orthopaedic department had performed and participated in several clinical trials on treatment of hip fractures, but no improvement programme had been conducted for this patient group. Although we knew our institution complied with national quality indicators for early surgery of hip fractures within 48 hours of admission, no assessment of other evidence-based measures existed. This knowledge gap led one of our senior staff members to initiate an improvement programme examining important processes in the treatment of hip fracture patients. We wanted to achieve sustainable improvement to the treatment pathway for elderly hip fracture patients by implementing a quality improvement (QI) programme based on evidence-based best practice elements. The improvement programme was designed so that all elements should be measurable and would represent an evidence-based substantial improvement if accomplished. To achieve such an improvement, we worked to involve all groups participating in the care of our patient group. With all involved parties felling ownership to the treatment, we aimed to achieve long-term adherence to the new processes. Our overall goal was to improve the quality and safety of the care process with our QI programme, thereby reducing the rate of complications, reoperations and mortality in this frail patient group.

METHODS

Quality improvement initiative

Background

The improvement programme was initiated by a senior staff member, anchored in hospital management and the different professions involved in the processes, and received improvement guidance from both internal and external experts when needed. Sustainability was promoted by distribution and visualisation of control charts on programme adherence, accompanied by supporting leadership comments. Continual information about best practice was provided by recognised professionals leading the improvement processes in a way that made sense to the different environments. We formed a multidisciplinary QI team consisting of an orthopaedic surgeon, orthopaedic and geriatric nurses, two representatives from the hospital trusts' quality improvement department, a physiotherapist, a geriatrician and an external reviewer with experience from previous QI teams. For the first 6 months, a management consulting firm with experience in QI work in healthcare conducted workshops with the QI team. The QI team assessed and discussed multiple possible process measures for inclusion in the programme and selected six based on three criteria: (1) whether a best practice is established, (2) whether an effect is substantial if there is a gap that is closed, and (3) measurability (figure 1).

The pilot

The QI team performed a pilot study examining 101 consecutive patient records to assess the baseline situation for these six process measures, performed interviews with key personnel, and then started developing the improvement programme. Based on the pilot study and interviews, we learnt that some programme elements were in place but not systematically measured, and several elements were not implemented at all. In light of the results of the pilot study, action was taken to close the gap

Intervention	Aim	Improvement effect
Early surgery	Surgery within 48 hours	Lower mortality
Infection prevention	Correct antibiotic prophylaxis	Reduced reoperation rate
Surgical method	Cemented arthroplasty in all displaced femoral neck fractures	Reduced reoperation rate
Surgeon experience	Always 2 surgeons and one senior surgeon in all arthroplasty and complex surgeries	Reduced reoperation rate
Multidisciplinary approach	Multidisciplinary team involved in all hip fracture patients >70 years	Reduced fall rate and complications
Secondary fracture prevention	Osteoporotic assessment and prophylaxis in all hip fracture patients	Reduced secondary fractures

Figure 1 Interventions in the improvement programme.

between current and best practice. Our intervention was conducted by a systematic approach of Plan-Do-Study-Act (PDSA)-cycles: Planning the changes, Doing (testing before implementing) the changes and measurements according to the plan, *S*tudying the result, *A*cting on the findings, and Planning the next round, based on what we have learnt from the previous round of the cycle.[32] The PDSA cycle is a well-known and commonly used improvement tool in healthcare settings, although its documented use in pragmatic clinical research has been rare.[33] Each process was changed to best practice according to evidence found in the literature and national guidelines. The target processes were monitored by a checklist and displayed by a control chart. After a review of the data in each PDSA cycle, we adjusted our approach accordingly to increase adherence.

The QI-program

The pilot study showed that the first two items, surgery within 48 hours and correct antibiotic prophylaxis, were well established beforehand, and were followed up by measuring sustainability of adherence together with the other programme items. The next two interventions were established by the department leadership: A department-wide rule of cemented arthroplasty in place of uncemented was enforced, as well as two surgeons, one being a consultant (more than 6 years of experience), participating in all arthroplasty and complex fracture surgery. Implementing an orthogeriatric care pathway with an interdisciplinary team took time and depended on collaboration with the department of internal medicine who had participants in the QI team from the beginning. Financial support for one geriatrician and one occupational therapist was secured in Q1 2014. A secondary fracture prevention system based on the FLS model was established so that all six interventions were in place by April 2014.

The QI team met on a monthly basis and worked throughout 2013 and 2014 to assess implementation progress and evaluate the need for modifications of the checklist and the interventions. We wanted to study the improvement process over time by monitoring the healthcare professional' adherence with the improvement programme by using a statistical process control chart (SPC). The programme was aimed at all hip fracture patients, and by the help of a checklist (figure 2), the programme was tailored to the individual patient's situation.

Adherence to the improvement programme was measured before, during and after testing and implementing the different elements. In addition, since patients operated with hemiarthroplasty were subjected to all six improvements, they were selected for follow-up for outcome measures: complications, reoperations and time from index operation to death. The outcome measures

Admitted: Date:		Time:		Activity		Evaluation				Notes and comments
Operation start: Date:		Time:		Executed		If yes		If no		
Registered by (initials):				Yes	No	Right	Wrong	Right	Wrong	
1. Early surgery										
1) Operated within 48 hours?										
2. Infection prevention										
2a) Correct antibiotic prophylaxis prescribed?										
2b) Time for each dose noted in chart?										
2c) Each dose administered on time?										
3. Surgical method										
3a) Operated with correct method? (Undisplaced femoral neck fracture: Screws. Displaced femoral neck fracture: Cemented arthroplasty. Trochanteric fracture: Sliding hip screw or nail)										
4. Surgeon experience										
4) In complex fractures and arthroplasty: Operated by two surgeons, at least one senior?										
5. Multidisciplinary approach										
5a) Screened for inclusion in multidisciplinary care?										
5b) Admitted in multidisciplinary part of ward?										
5c) Assessed in multidisciplinary team meeting?										
5d) Assessed by geriatrician?										
6. Secondary fracture prevention										
6a) Secondary fracture assessment performed?										
6b) Medical osteoporosis prophylaxis administered or prescribed?										
6c) Standardised phrase for secondary prevention assessment used in discharge report?										

Figure 2 The checklist used for SPC measurements of compliance. SPC, statistical process control chart.

were collected in a before and an after group, the cut-off being the implementation of all six improvements.

Statistical process control

During the seven periods of the study, an individual chart for SPC (I-chart) was selected to display and understand the variations in the professional adherence over time with the six changes that were tested and implemented. The I-chart was updated and analysed by standard rules to detect any signal of special cause variation in the wake of the changes we were testing.[34 35] Making patients safer also involves variation according to their individual needs.

Therefore, we provided adherence scores only where the care had been tailored to the individual patient's situation (figure 2). To assess the sustainability of the achievements from 2016, an additional SPC measurement was conducted in 2021.

Impact of QI initiative

Outcome measurements

To study the impact of the improvement programme, we compared the period for outcome measures before all items were implemented (January 2012–March 2014) with the period after April 2014–December 2015. To compare the two groups at baseline, we collected data by chart review on age, gender, ASA classification, diabetes, smoking, dementia, alcohol abuse, number of medications, body mass index (BMI) and operating time. We also investigated whether the patient lived in an institution, and if not, whether they had any form of aid in their home before the fracture. Finally, we examined the timing of surgery, dividing the day into the three main hospital shifts, morning, evening and night. Since a change from uncemented to cemented hemiarthroplasty was one of the six parts of the improvement programme, only patients with a dislocated femoral neck fracture, and therefore in need of a hemiarthroplasty, were chosen for investigation with regards to outcome. Patients with undislocated femoral fractures and pertrochanteric fractures were treated with osteosynthesis and were, thus, not eligible for outcome measurements although they received the five remaining parts of the programme.

Statistical analysis

Complications, reoperations and mortality were recorded up to 5 years after index operation. Survival curves were compared using log-rank (Mantel-Cox) test and reported as HRs with 95% CIs.

Missing data

BMI data were frequently missing, both in the admittance chart and the anesthesiology report. Only 323 of 476 charts (68%) contained weight and height of the patient. There were 98 (34%) missing in the before group and 55 (30%) in the after group. Other than BMI, we were able to attain complete data on all patients.

Patients and public involvement

This research was conducted without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient-relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

RESULTS

Quality improvement initiative

All patients operated with a hemiarthroplasty in the period from 2012 to 2015 were investigated for outcome. There were 293 in the before implantation of changes group, and 182 patients in the after implementation of changes group. Comparing the patient characteristics before and after the intervention, we found no major differences between the groups (table 1).

Statistical process control

At baseline adherence to our set of evidence-based improvements was 45%. The first measurement after implementation of our guidelines showed an improvement to 58%. In total, we found three significant shifts of level in the desired direction, by more than eight consecutive data points above the previous centre line in each change period, towards sustainable, almost full adherence to the QI programme. Seven years later, the improvements appeared to be fully integrated in the department's treatment algorithm with 96% adherence (figure 3), without the need for further interventions from the QI-team, thus indicating a sustainable improvement had been achieved.

Impact of the QI initiative

Outcome measurements

Our results showed a 60% reduction in major complications after the implementation of the improvement programme, from 19.1% to 7.7% (HR: 0.38 (95% CI 0.23 to 0.61, p=0.0007) (table 1, figure 4). The need for a new surgery because of a complication fell from 12.6% to 4.9% (HR: 0.37 (95% CI 0.21 to 0.67, p=0.0054) (table 1, figure 4). In the before group, 60% of the complications occurred before 30 days postsurgery, whereas 43% occurred within 30 days in the after group. We further examined the need for new surgery and found that 65% of the reoperations was performed within 30 days in the before group. In the after group, 22% was performed within 30 days. Regarding postoperative mortality, we were not able to show any difference (HR: 0.95 (95% CI 0.74 to 1.2, p=0.645) (figure 4).

Other effects of the program

With the implementation of two surgeons for all hemiarthroplasties, one being a consultant, we saw a change towards more surgeries being pushed from the night shift to the next morning. Before all interventions were implemented, 35 of 293 (11.9 %) hemiarthroplasties were performed during the night shift, whereas only 8 of

Table 1 Patient characteristics, complications and reoperations

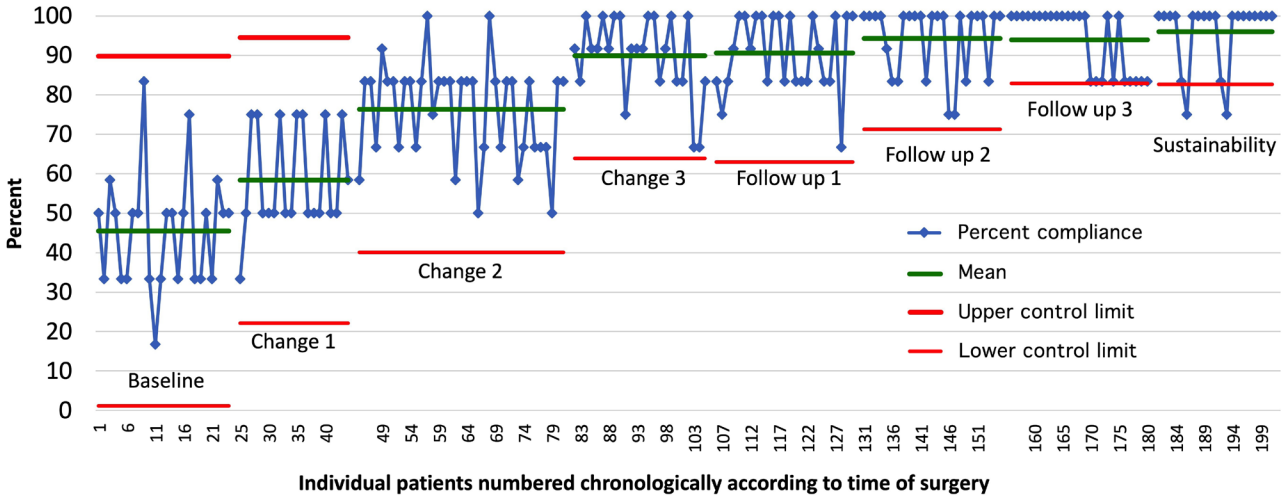
Patient characteristics	Before intervention (n=293)	After intervention (n=182)	Hazard ratio (95% CI)	P value
Mean age (SD)	83.2 (8.5)	83.5 (8.0)	–	0.69
Male sex, n (%)	94 (32.1 %)	49 (26.9 %)	–	0.23
Mean BMI (SD)	22.9 (4.2)	22.5 (3.7)	–	0.39
ASA 1, n (%)	4 (1.4 %)	2 (1.1 %)	–	0.87
ASA 2, n (%)	101 (34.5 %)	65 (35.7 %)	–	
ASA 3, n (%)	175 (59.7 %)	105 (57.1 %)	–	
ASA 4, n (%)	13 (4.4 %)	11 (6.0 %)	–	
ASA 5, n (%)	0 (0.0 %)	0 (0.0 %)	–	
Mean number of prescribed drugs (SD)	4.9 (3.5)	4.8 (3.3)	–	0.86
Diabetes, n (%)	24 (8.2 %)	16 (8.7 %)	–	0.82
Smoking, n (%)	38 (13.0 %)	17 (9.3 %)	–	0.22
Alchohol abuse, n (%)	12 (4.1 %)	5 (2.7 %)	–	0.42
Dementia, n (%)	71 (24.2 %)	35 (19.1 %)	–	0.20
From institution, n (%)	75 (25.6 %)	58 (31.7 %)	–	0.15
Living at home with aid, n (%)	68 (23.2 %)	44 (24.0 %)	–	0.35
Mean operating time, min (SD)	70 (24.6)	72 (15.3)	–	0.20
Complications				
Dislocation	26 (8.9 %)	8 (4.4 %)	0.48 (0.24 to 0.96)	0.066
Infection	9 (3.1 %)	2 (1.1 %)	0.32 (0.1 to 1.02)	0.12
Dislocation with infection	5 (1.7 %)	1 (0.5 %)	0.32 (0.62 to 1.66)	0.27
Periprosthetic fracture	14 (4.8 %)	3 (1.6 %)	0.34 (0.13 to 0.9)	0.074
Other	2 (0.7 %)	0 (0.0 %)	0.2 (0.01 to 3.42)	0.26
Total	56 (19.1 %)	14 (7.7 %)	0.38 (0.23 to 0.61)	0.0007
Reoperations				
Dual mobility acetabular cup revision to prevent further dislocations	14 (4.8 %)	2 (1.1 %)	0.23 (0.08 to 0.62)	0.031
Soft tissue debridment with exchange of prosthetic heads	9 (3.1 %)	2 (1.1 %)	0.35 (0.11 to 1.19)	0.16
Osteosynthesis and/or change of femoral stem	8 (2.7 %)	3 (1.6 %)	0.6 (0.18 to 2.01)	0.44
Girdlestone (removal of implant)	6 (2.0 %)	2 (1.1 %)	0.53 (0.13 to 2.22)	0.43
Total	37 (12.6 %)	9 (4.9 %)	0.37 (0.21 to 0.67)	0.0054

183 (4.4 %) were performed at night during the period after implementation. This increased the need for more available time in the operating theatre during daytime, to maintain the time from admittance to surgery below 48 hours. To accommodate this, a surgical slot was reserved each morning specifically for hip fracture surgery. Because surgical slots are not infinite, this was at the expense of other surgeries and thereby patients.

DISCUSSION

Adherence to our six evidence-based improvements increased from 48% to 94% in the study period. We could also show sustainability of the whole process with 96% adherence 5 years after the project was finished. We found a 60% decrease in major orthopaedic complications. We also found a decrease of 61% in the need for a reoperation due to a complication. We could, however, not show a change in the overall death rate. This, we believe, is mainly due to the overall health condition in the patient group before the fracture. Almost 25% of our patients suffered from dementia, and over 60% were ASA 3 or higher at the time of surgery, indicating frailty before the fracture. We, however, argue that all of the complications investigated have a major impact on quality of life for the individual patient as well as being highly expensive for the hospital and, thus, the society. Therefore, we have reason to believe that our improvement programme has improved the quality and safety of the care of one of our most fragile and vulnerable patient groups as well as cutting healthcare costs.

The most serious complications after hip fracture surgery are dislocations, periprosthetic fractures, deep infections and death. Reporting on complication rates varies in the literature ranging from 12.5% to 75%,[36–39]



Period	1	2	3	4	5	6	7	8
Activity	Baseline	Change 1	Change 2	Change 3	Follow up 1	Follow up 2	Follow up 3	Sustainability
Date	March 2013	March 2014	May-Jun 2014	March 2015	Sep-Oct 2015	Mar-Apr 2016	Aug-Oct 2016	March 2021
N	24	20	37	24	25	25	25	21
Mean	45	58	76	90	91	94	94	96
UCL	90	95	113	116	118	117	105	109
LCL	1	22	40	64	63	71	83	83

Figure 3 I-chart showing per cent compliance of the improvement programme, before, during and after the changes were tested and implemented. The graph shows consecutive hip fracture patients according to date of surgery in eight measurement periods, indicating three significant shifts of level in the desired direction in period 2, 3.

but differences in how and which complications are reported make it difficult to compare results. Most traditional studies, and all randomised controlled trials, focus on singular risk factors out of many, after hip fracture surgery. In this study, we wanted to release the full might of the quality improvement toolbox. A major strength in using this quality improvement strategy, and underpinning the interventions by recognised improvement knowledge, is making it possible to change multiple processes during a short period of time. We also chose interventions that were to some degree interrelated, yielding a likely positive synergistic effect.

A major strength in our study is the use of continual measurements of adherence with the programme and using PDSA cycles for tweaking the processes when necessary. We can, therefore, know with certainty that the changes in the treatment pathway were being followed, and a direct correlation with the improvement programme and the decrease in complications can be derived. We were also able to follow the new processes towards almost certain sustainability 7 years later, showing that the changes had been integrated in our standard care of hip fracture patients.

When implementing large-scale changes to any system, there are several factors that need to be considered. Anchoring in management is essential, without which change is impossible. The next step is creating a shared understanding of the rationale behind the changes among all staff involved in the system. Therefore, the changes needed to be evidence based and continually taught. Finally, one or several champions for the cause are needed to properly explain, correct and follow-up the changes until the processes are stable. In our opinion, our success is mainly due to the fact that we had all three of the above-mentioned elements in place. We had anchoring in the entire patient pathway management, we had understandable and evidence-based reasons for changing our processes, and we had champions for the cause following and explaining the processes for several years after their implementation. Our group worked continually to involve and educate all groups involved in processes both directly and indirectly connected to care of patients with hip fracture. By conveying ownership to the processes involved to the individual healthcare professional groups, we aimed to, and succeeded, in achieving a sustainable improvement. By educating management, we were also able to make structural changes to our organisation with a day slot for hip fracture surgery and organisation of an orthogeriatric team and an FLS team. This eased rather than increase the burden on the individual staff member making the changes possible to implement and sustain.

LIMITATIONS

As with all QI studies, it is not possible to identify which intervention had the largest impact on our results. One could argue that one or two of the six interventions alone may have yielded the same results, but with two of the six interventions in place at baseline, we would argue that

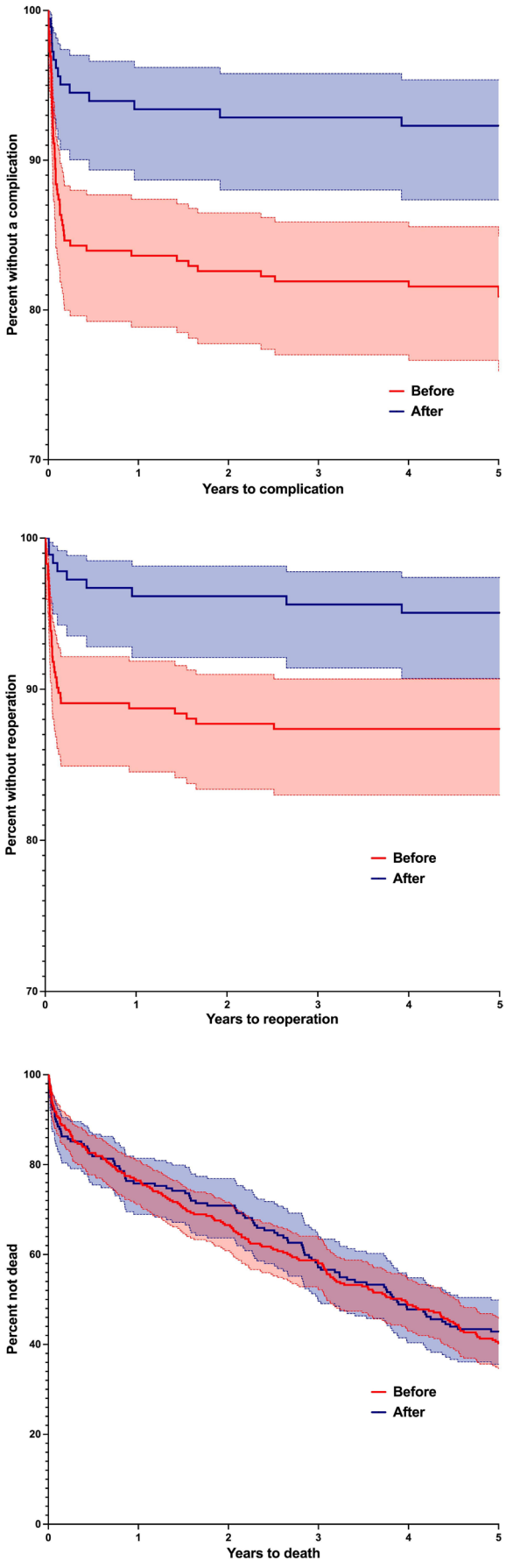


Figure 4 Survival graphs comparing complications, reoperations and mortality between the period before and after all interventions were in place.

all of the interventions and the probable effect of the QI work itself, all have synergetic effects.

Overstandardising can increase risks for individual patients. Our approach to this was to allow for variation and grant points in the checklist when there was a medical reason for swaying from the programme. This opens for interpenetrations by the data recorders and, thus, bias issues.

Control charts are powerful tools for understanding the variation of a target process, but as the adherence data evolved to be more and more dichotomous during the improvement progress, the I-chart lost its power for analysing variation in periods 7 and 8. However, the chart is displaying an almost full adherence to the QI programme up to 7 years after the last changes were made. A p chart on the main adherence proportion per week would statistically have been more appropriate for this kind of data. However, the large amount of data to collect would have strangled the improvement process. We also did not set specific goals for adherence to our interventions before starting the study. In retrospect, we ask ourselves whether the QI work may have benefitted from clearly articulated adherence goals.

There is no consensus on what the best form of orthogeriatric treatment should be. Local adaptations are necessary, but there may be other more effective approaches for this group of patients, than ours. Some studies have managed to show reduced mortality rates with the implementation of an orthogeriatric treatment pathway.[21 40] Why we could not, remains a question of interest to us.

CONCLUSIONS

Medical treatments are becoming more and more complex. There is an increasing need for a comprehensive and systematic approach to all individual patient treatment and pathways. In this QI project and study, we focused on a frail patient group of individuals with compound health issues, where margins are small and complications can be catastrophic. Known risk factors in hip fracture patients are intertwined, and, thus, the focus should be on all aspects of the treatment to prevent serious complications. The multidisciplinary approach with improvement efforts in several key areas following best practice is essential to provide optimal healthcare for these patients. We argue that our six interventions were interacting towards a synergistic effect, yielding an outcome that was better than the sum of its parts. The good results and the recognised improvement knowledge underpinning the intervention indicates its effectiveness and generalizsbility to other hospitals.[41] However, the quality of the spread will depend on the other hospitals' ability and patience to tailor the intervention to their particular context.[42]

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Patient consent for publication Not applicable.

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ORCID iDs
Tom Lian http://orcid.org/0000-0003-0087-5598
Aleidis Brandrud http://orcid.org/0000-0002-4161-5760

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