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What makes the best performing hospital? the IQ Joint study

Schie, P. van

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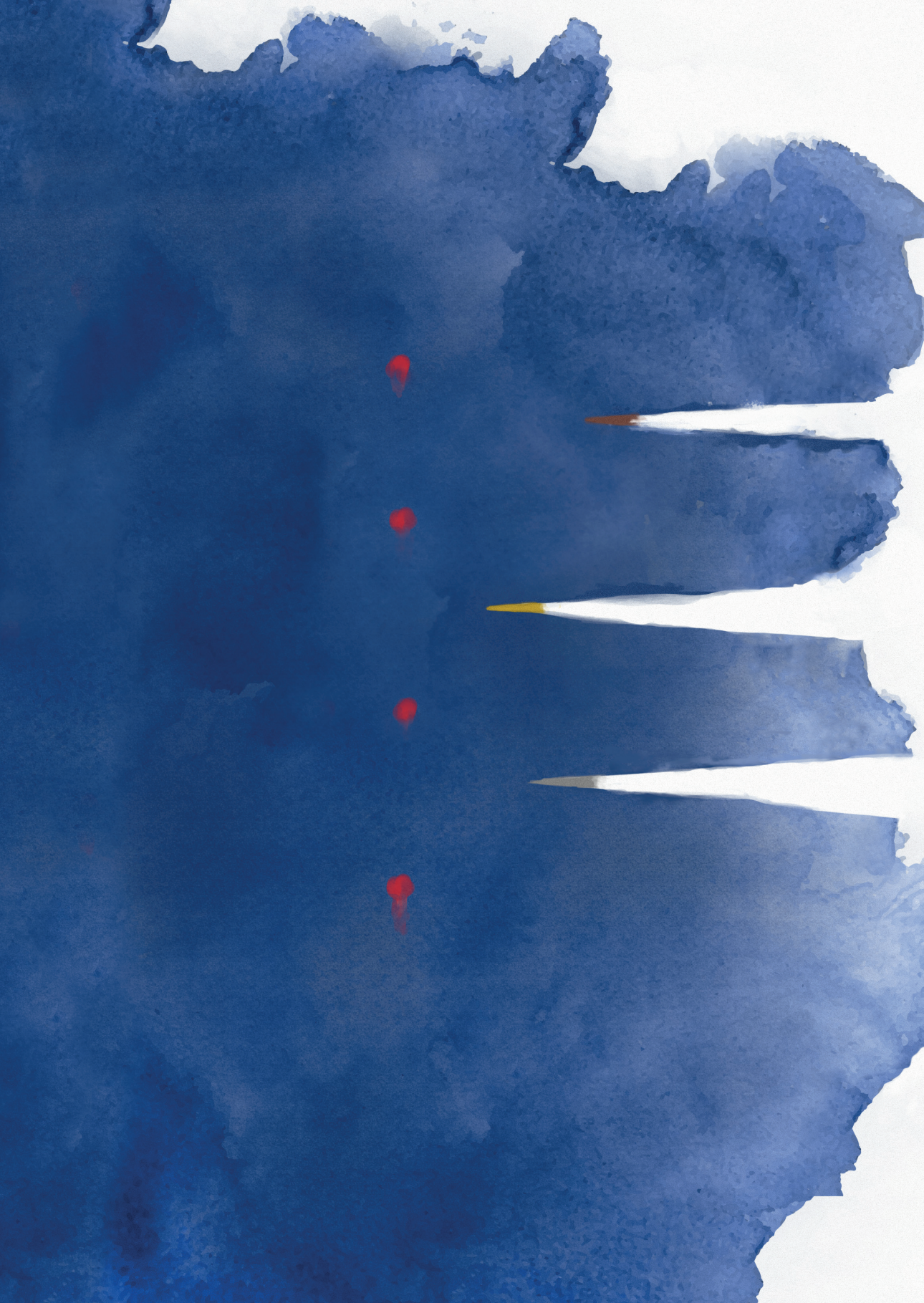

Chapter 1

General introduction and
outline of the thesis

Background

Total hip and knee arthroplasties (THA and TKA) are the most successful treatments for end-stage hip and knee osteoarthritis and are among the most common surgeries performed worldwide.(1-8) In the Netherlands, more than 33,000 THA and 34,000 TKA are performed yearly. The number of procedures is expected to increase exponentially in the coming decades due to the ageing population and the increasing prevalence of obesity.(9-12) As a result, the number of adverse events such as revisions will rise, increasing not only the burden to patients but also the burden on healthcare systems and thus society.(10,13-17) It thus becomes even more critical to improve clinical outcomes for arthroplasty surgery, such as revision, readmission, complications, and length of stay (long LOS) by delivering high-quality care to these patients.

Since the earliest recorded attempt at total hip and knee arthroplasty by Professor Glück in 1891, the most significant improvement in clinical outcome rates were achieved by the ongoing process of implant improvement.(18,19) For that matter, the first hip implants made of ivory were unsuccessful due to severe postoperative pain and high revision rates due to prosthesis loosening; these implants were replaced by a hollow ball of glass that fits over the femoral head in 1923.(20,21) However, the glass could not withstand the hip joint forces and shattered. Subsequently, experiments with materials for hip implants were done with several materials (e.g., Bakelite, Pyrex, Viscaloid, Vitallium, and metal).(22,23) Professor Sir Charnley was the first who successfully performed a THA in 1960, the basic principles he used still apply today (Figure 1).(24) For TKA, Insall and Burstein in the US and simultaneously Yamamoto in Japan developed the prototype of a new knee implant concept in 1971, resurfacing all three knee joint articular surfaces (i.e., femur, tibia, and patella) (Figure 2).(25) However, even though clinical outcomes have improved considerably since these first successful THA and TKA prototypes, clinical outcome after surgery does not only depend on implant design but also the quality of care delivered to the patient.

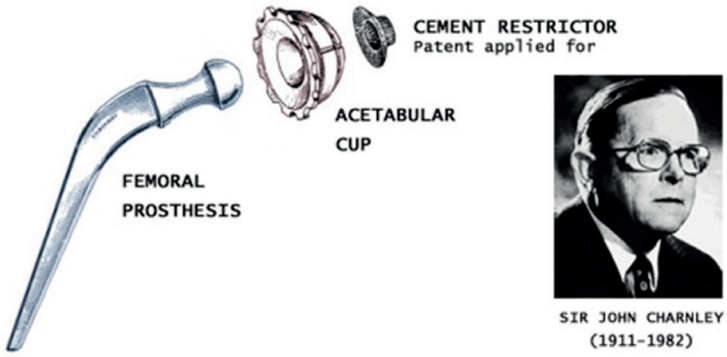

Figure 1 Charnley hip replacement
Charnley's design consisted of a metal (stainless steel) femoral component and a Teflon acetabular component; both were fixed to the bone using bone cement (acrylic).

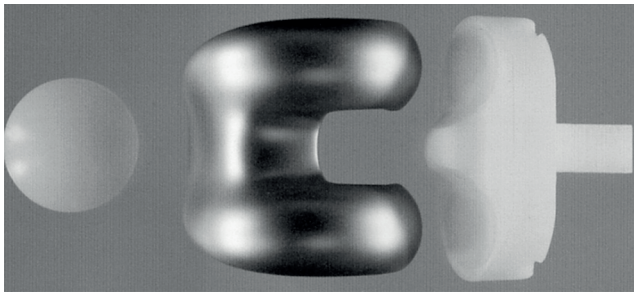

Figure 2 Insall-Burstein knee implant
Insall and Burstein's total condylar implant. The patellar button is shown at the top, the femur component in the middle, and the tibial component at the bottom.

In orthopaedics, revision surgery is the most commonly reported clinical outcome measure following THA and TKA because of the dramatic consequences for the patient and the considerable cost involved.(26,27) During such revision surgery, some or all of the primary joint components are replaced by new parts. Furthermore, revision surgery is a longer and more complex procedure than primary arthroplasty surgery, with less favourable outcomes such as higher infection rates and worse function compared with the primary procedure.(28,29) A revision within one year is a widely used clinical outcome to monitor the quality of care delivered, as it is close to the primary surgery performed and, as such likely related to the quality of care delivered during and after that primary surgery. In contrast, a revision within 5 years

is less likely to be related to the quality of care delivered but more relevant to track implant survival.

Dutch arthroplasty register

The Dutch Arthroplasty Register (LROI), established in 2007 by the Netherlands Orthopaedic Association (NOV), started with the registration of hip and knee implants.(9) In 2014, the implants for the shoulder, elbow, and ankle, and Patient Reported Outcome Measures (PROMs) for hip, knee, and shoulder were added. In 2016 the register was further expanded with data collection for wrists and fingers. The initial primary purpose of arthroplasty registries was to compare performance, defined as survival, of different types of implants and detect worse-performing implants earlier to promote patient safety. A well-known example of the latter was the detection of the metal-on-metal (MoM) hip arthroplasty disaster. The latter was identified by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) as having an outlier performance in 2007.(30) Twenty percent of patients had to undergo a revision within ten years, compared with four percent in the "classic" metal-on-polyethylene arthroplasties.(31,32) The mortality risk increased by 8.5% (95%-CI: 5.8%-11.2%) due to these implants.(33) These MoM implants were withdrawn from the market in 2010, showing the value of registry data to ensure safety. Another advantage, besides the ability of registries to flag bad-performing implants, is that implants can be traced back to the patient in case of a calamity as the implant number of each implant component and a personal encrypted security number for each patient are collected.

In recent years, registries have also been used to monitor the quality of care delivered by orthopaedic groups/clinics by tracking clinical outcomes (e.g., revision) of hospitals, with the aim to improve performance by providing hospitals with feedback on their outcomes.(9,34-36) The LROI provides feedback on case-mix adjusted revision rates, Patient-Reported Outcome Measurement (PROM) difference scores, and patient characteristics at the hospital level, which are reported on a secured web-based dashboard annually. Connected to that feedback, the LROI and the NOV started a "Quality commission" in 2017 that actively approaches poorly performing hospitals (i.e., negative outliers) to discuss quality improvement initiatives (QII) and create action plans to improve.(37) The commission includes a team of clinical experts visiting hospitals with unfavourable results to advise and help them start improving the quality of care delivered.(37)

Registry data can be used reliably for monitoring the quality of care delivered if coverage (i.e., the proportion of hospitals reporting to the register), completeness (i.e., the proportion of included patients in the register), and validity of data are good. The LROI coverage is 100% as all hospitals upload their data. Data completeness is checked against Hospital Electronic Health Records and currently exceeds 99% for primary procedures and 97% for revisions, meaning that >99% of primary procedures are included.(38) To increase validity, the LROI has implemented several steps, such as mandatory boxes in the web-based registration form and automatically generated reports when one or more variables are missing or inconsistent. The validity is currently 93% for THA and 96% for TKA.(39) The patient's vital status (dead or alive) is obtained from the Dutch insurance healthcare database Vektis, which is needed to calculate implant survival. The opt-out system for informed consent is applied, whereby patients must actively object not to be included.

Feedback using registry data

Arthroplasty registries, including the LROI, provide feedback to orthopeadic surgeons, which is intended to improve the quality of care delivered.(40,41) The variation in performance between hospitals on clinical outcomes is usually reported compared to a reference standard (i.e., the benchmark) that indicates whether performance in that specific clinic is comparable to the predefined benchmark or deviates from it. The total population of interest (i.e., national average on revision for TKA or THA etc.) with a specific norm is often chosen as the benchmark for comparison. The most commonly used clinical outcomes for feedback are revision, readmission, and complications, as these indicators are considered reliable, actionable, and fit for purpose.(42-47) Providing feedback is based on the belief that orthopaedic surgeons are prompted to modify their practice when performance feedback shows that their clinical practice outcome measures deviate from the desirable benchmark target. Feedback is not only aimed at underperforming hospitals but also at average or high-performing (i.e., best-practices) hospitals with the rationale that there is always room to improve further. In addition, hospitals can learn from better-performing hospitals by engaging and adopting items from these best practices. However, there may be less incentive to improve further for hospitals among the best-performing hospitals in their own country. These hospitals may be interested in comparing their outcomes with hospitals from other countries or healthcare systems to stimulate further improvement. The latter is only possible if there is consistency in the clinical outcome definitions and methods used to collect data across countries or healthcare systems, as these will determine the frequency of occurrence of end-point definitions (i.e., events) of the benchmark. Furthermore, the occurrence of clinical outcomes

should be adjusted for differences in patient characteristics that determine the risk of these outcomes, to achieve a fair hospital comparison. For example, healthy patients (e.g., ASA I patients with osteoarthritis) are expected to have a lower frequency of adverse clinical outcomes (e.g., revision) than patients with multiple comorbidities (e.g., ASA IV patients with congenital hip deformities).(48-51) Therefore, in case of hospital comparisons across countries, it will have to be assessed whether the same patient characteristics are available in all countries for risk adjustment.

Funnel plots with control limits are commonly used as a graphical tool to show between-hospitals variation for clinical outcomes (Figure 3). Hospitals plotted between the two control limits have a performance that is not statistically different from what is expected based on their patient characteristics. Hospitals plotted above the upper control limit have more events observed than expected and are negative outliers when considering adverse outcomes like revision; vice versa, hospitals plotted under the lower control limit have fewer events observed than expected and are positive outliers. Nowadays, multiple years of clinical outcome data (e.g., revision, readmission, and complications) are usually combined to obtain detectable and reliable differences in hospital performance due to low event rates.(9,34-36,52-57) The LROI and other arthroplasty registries typically combine three years of data. Therefore, it may take long before deteriorating performance is noticed, resulting in late action plans to improve care. However, if the reliability of ranking hospitals using single years of data is acceptable, a reliable earlier signal can be given when performance deteriorates. In addition, hospitals may be underperforming for all-cause revision, which may be due to various underlying causes. For example, hospitals may have higher infection, dislocation, implant loosening, or technical failure rates. To connect with subsequent targeted QII, it is relevant whether hospitals are an outlier for specific revision indications rather than only reporting outlier status on the all-cause revision rates. Assessing whether hospital performance can be reliably distinguished for revision indications may therefore be a step forward.

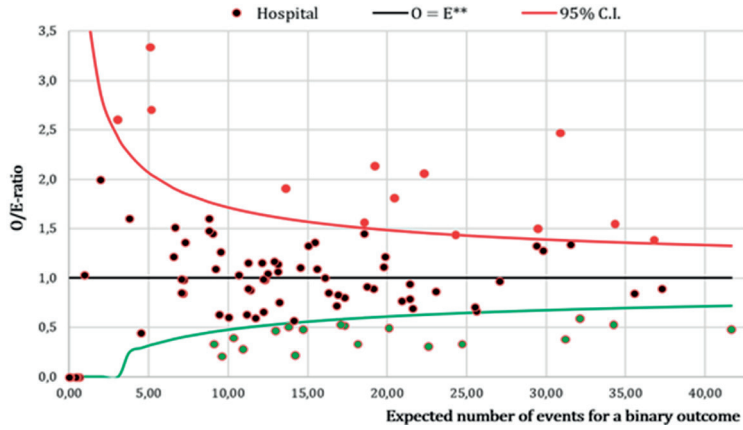

Figure 3 Example of a funnel plot
Each point represents a hospital. The O/E-ratio is described on the y-axis, and the expected number of events per hospital on the x-axis. The red line is the upper control limit, and the green line is the lower control limit. When O/E-ratio is equal to 1, the observed number equals the expected number of events in a hospital.
O/E=observed number of revisions divided by the expected number of revisions.

A second opportunity to detect underperforming hospitals earlier is using statistical approaches other than the traditional funnel plot, where the aggregate performance over a period is shown rather than the development over time. Several clinical studies have led to growing interest in Statistical Process Control charts such as the Shewhart-p-chart and cumulative sum (CUSUM) chart, which can distinguish between an "in-control" process, showing only random (chance) variation over time and an "out-of-control" process, showing systematic (special-cause) variation by generating a signal (alert) at a specific point in time when the control limit is reached (Figure 4).(58-69) The Shewhart p-chart is considered an accessible chart, especially concerning implementation and straightforward interpretation.(70) However, the CUSUM chart has superior performance in detecting small (<10%) and significant (>10%) increases in event rates.(65,70-72) These two SPC charts thus seem logical alternatives for the funnel plot. The CUSUM chart is used to identify higher complication rates after THA and TKA in Scotland.(69) However, that study did not report how much earlier a signal was generated and with what accuracy compared with the traditional funnel plot presentation of events according to the benchmark.

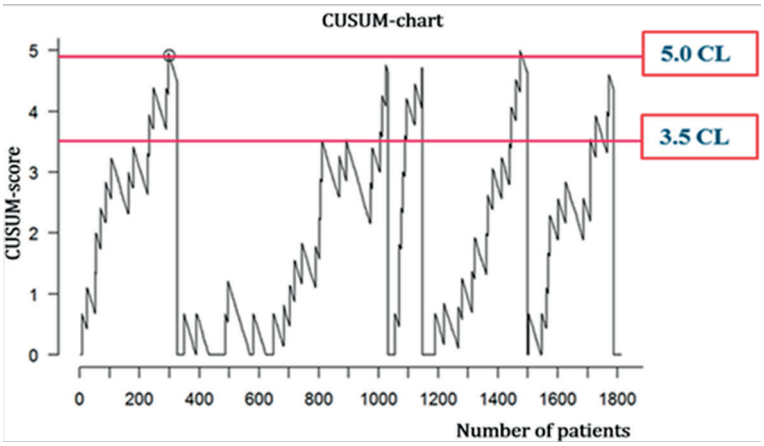

Figure 4 Example of a CUSUM chart
The CUSUM chart for a single hospital is shown. The observed minus expected probability for an event is plotted for every consecutive patient. When the score goes upward, this means that the observed performance for that patient is worse than expected, vice versa when going down. A single (alert) is generated when crossing the CL. A higher CL (5.0) means increasing certainty that this is a valid signal with fewer false-positive signals but could miss cases of worse performance. The opposite applies to lower CL (3.5).
CL=control limit; CUSUM=cumulative sum.

A third opportunity to obtain an earlier signal is to combine multiple relevant clinical outcomes into one composite outcome measure to achieve a higher number of events per hospital, thereby increasing the accuracy by which hospital performance is estimated. Feedback by arthroplasty registries is primarily provided on single clinical outcomes (e.g., revision, readmission, or complications). Using a composite outcome may take less time to differentiate between hospitals in their performance reliably.(73-76) Furthermore, single outcomes provide only a partial view of the quality of care delivered, as a hospital may have a high score on one outcome but may need to improve on another.(9,34-36,52,77-79) Because of these limitations, there is growing interest in composite measures, in which multiple relevant outcomes are combined to provide a more comprehensive overview of the delivered quality of care. However, existing composite outcomes often represent a binary all-or-none concept. These measures are less useful for quality improvement since they give equal weight to all clinical outcomes. In contrast, from a patient's perspective, revision is probably more important to avoid than, for example, upper-quartile LOS. In addition, these all-or-none composite outcomes do not provide feedback on where to improve (i.e., for which combination of outcomes), and do not take into account the possible interrelationship between individual clinical outcomes.(73,76,80,81)

Sofar, the focus on providing feedback in arthroplasty registries has mainly been concentrated on "passive" reporting clinical outcomes that measure the unintended effects rather than the intended outcomes of pain reduction, improvement in functionality, and improved health-related quality of life. Ten and 20% of patients following THA and TKA, respectively, are not satisfied with postoperative results, mainly related to persistent pain and disability.(82,83) The proportion of patients achieving a clinically relevant improvement is not routinely used as hospital feedback in most arthroplasty registries due to low response rates that vary between hospitals. Most arthroplasty registries collect PROMs, but response rates (i.e., patients who completed the PROM questionnaire) are often low compared with above 95% completeness of data for clinical outcomes.(84-89) It is unclear in which direction missing PROM scores bias results on clinically relevant improvements. In addition, despite using Patient-Reported Outcome Measures (PROMs) for a long-time, it remains unclear whether clinically relevant improvement in PROM scores reflects the quality of care delivered as measured by well-known clinical outcomes (i.e., revision, readmission, complications, and upper-quartile LOS).(90) For example, a readmission may affect postoperative PROM scores and thereby the improvement achieved, which would suggest that hospitals reducing their readmission rates may also increase the proportion of patients receiving clinically relevant improvements. If these are unrelated, improvement of PROM scores should be achieved in a different direction, e.g., in management of pre-operative expectations.

Improving the effectiveness of feedback using registry data

Arthroplasty registries have been used worldwide to give surgeons and hospitals feedback on their performance, aiming to improve the quality of care delivered. (9,34-36,52,77-79,91) The LROI provides such feedback on a secured web-based dashboard at the hospital level, which is updated annually. However, feedback is only effective when surgeons are aware of their performance. The awareness of overall defined performance on surgical procedures among orthopaedic surgeons performing THA and TKA in the Netherlands is unknown, as well as factors associated with their awareness of this overall performance. Reasons might be that it is too time-consuming for orthopaedic surgeons to log into the LROI dashboard, so that feedback should be sent differently (e.g., by email or presentation), or surgeons may need education to (mis)interpret the graphs (i.e., funnel plots). The latter also prevents wrong interpretation and thus conclusions regarding their clinic's performance data. They may also be interested in other clinical outcomes than revision (e.g., readmission, complications, and upper-quartile LOS) or require the feedback to be tailored to their surgeon group rather than making selections themselves in an online dashboard.

Surgeons often overestimate their own performance, assuming that performance is good even when there is room for improvement, which may limit the introduction of QII.(92)

Even though a necessary first step, awareness is not sufficient to make feedback effective. The effectiveness of feedback was evaluated in a Cochrane review, including 49 studies from multiple fields, and showed a median absolute improvement of 4.3% (interquartile range (IQR): 0.5% to 16.0%).(41) Although the median effect size is relatively small, the 75te percentile effect size suggests that A&F, when optimally designed and used in the proper context, can play an essential role in improving clinical practice. The current literature shows that A&F is more effective when provided proactively in a multifaceted way, including for instance an action implementation toolbox to facilitate actions undertaken instead of a "passive" single element (e.g., feedback or education alone).(41,93-95) However, a previous study including such an action implementation toolbox only showed improvement in process indicators but not in patient outcomes, whereas the ultimate goal is to improve patient outcomes. (95) In addition, it should be mentioned that even a relatively small improvement for THA and TKA will have a significant societal impact considering the sizeable annual number of surgeries performed (I.e., approximately 70,000 THA and TKA only in the Netherlands annually).(9)

To support continuous quality improvement initiatives arising from feedback, the *Plan-Do-Study-Act (PDSA)* cycle is mostly used.(96) The cycle consists of four repetitive steps in which the main focus is the interpretation of feedback results, the introduction of QII, and the evaluation of its effect. Because the cycle can only be appropriately used when up-to-date feedback is available, it seems well-suited to be used by hospitals using registry-based feedback. The following four steps are distinguished within the PDSA cycle (Figure 5):

1. Detect opportunities for improvement based on feedback, and plan QII to improve care (*Plan*);

2. Implement the QII (*Do*);

3. Review whether the QII was implemented as planned, analyse the effect, and identify what is learned (*Study*);

4. If the QII did not work as planned, adapt the QII and go through the cycle again with a revised plan. If the QII was successful, incorporate what is learned. Use what is learned to plan a new QII, beginning the cycle again and continue further improvement of outcomes.

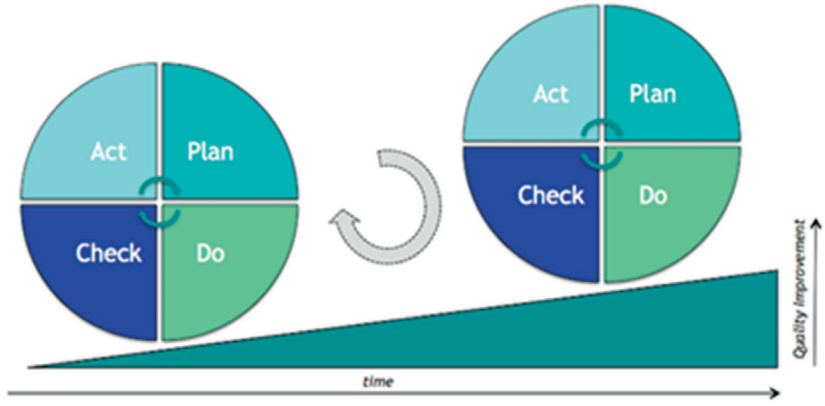

Figure 5 Plan-Do-Check-Act cycle

Outline of this thesis

This thesis aimed to study how arthroplasty registries can improve their feedback to surgical groups and its individual surgeons to give direction to QII that improve care of THA and TKA, and to test the effectiveness of such improved "active" feedback to improve patient outcomes.

In **chapter 2,** the literature was reviewed to assess the international variation between hospitals for revision, readmission, and complications. We focused on definitions used, data collection methods, and for which patient characteristics clinical outcomes were adjusted, to interpret the variation between hospitals. This will also show whether it is feasible for hospitals to compare their outcomes with other countries to stimulate further improvement.

To improve current registry-based feedback to surgical groups, **chapter 3** investigates the between-hospital variation for 1-year revision and specific indications for revision (i.e., infection, dislocation, implant loosening, and technical failure) to give direction to improvement initiatives and assess the reliability of ranking hospitals on their performance using 3 years or single years of data, with the latter enabling an earlier signal of deteriorating performance.

In **chapter 4**, the Shewhart-p-chart and CUSUM chart were tested to assess how much earlier and with what accuracy worsening hospital's performance in 1-year

revision rates can be detected, compared with the traditional funnel plots using three years of data.

In **chapter 5,** an ordinal composite outcome measure was developed with all combinations of clinical outcomes (i.e., revision, readmission, complications, and upper-quartile LOS) ranked from best to worst according to the patient's perspective, indicating more specifically where improvement is possible while also potentially increasing the ability to reliably differentiate between hospitals in their performance with fewer years of data. The reliability of ranking was therefore calculated for the composite and single outcomes.

Chapter 6 aimed to provide insight in how improvement in PROM scores may be under- or overestimated relative to all patients who received a THA or TKA. This was done by comparing PROM questionnaire respondents and non-respondents on their clinical outcome rates (i.e., revision, readmission, complications, and upper-quartile LOS). Furthermore, is was assessed whether patients experiencing an adverse clinical outcome had different improvement in PROMS scores as well as whether hospitals with better clinical outcome rates showed different improvement in PROM scores and PROMS response rates.

Improving feedback is only effective when it is seen and correctly interpreted by orthopaedic surgeons; only then do surgeons become aware of their performance and the need for quality improvement. **Chapter 7**, therefore, assessed the awareness of Dutch orthopaedic surgeons regarding their performance on revision and factors associated with this awareness, such as whether they could recall their revision rate, log in to the LROI dashboard at least once a year and the ability to interpret data presentation by a funnel plot correctly. In addition, it was investigated what surgeons wanted to be improved of the LROI feedback, such as additional clinical outcomes, mode of receiving feedback, and preferred frequency.

The knowledge obtained from all previous chapters combined with contemporary theory for providing effective feedback was incorporated into a multifaceted quality improvement intervention, including improved feedback on performance and interactive education combined with an action implementation toolbox containing evidence-based QII. This intervention was tested in a cluster randomised controlled trial on its effectiveness to improve patient outcomes, the results of which are reported in **chapter 8**. **Chapter 9** Includes a summary, general discussion, and future perspectives.

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