



Effectiveness of a multifaceted quality improvement intervention to improve patient outcomes after total hip and knee arthroplasty: a registry nested cluster randomised controlled trial

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ABSTRACT

Objective To assess the effectiveness of a prospective multifaceted quality improvement intervention on patient outcomes after total hip and knee arthroplasty (THA and TKA).

Design Cluster randomised controlled trial nested in a national registry. From 1 January 2018 to 31 May 2020 routinely submitted registry data on revision and patient characteristics were used, supplemented with hospital data on readmission, complications and length of stay (LOS) for all patients.

Setting 20 orthopaedic departments across hospitals performing THA and TKA in The Netherlands.

Participants 32 923 patients underwent THA and TKA, in 10 intervention and 10 control hospitals (usual care).

Intervention The intervention period lasted 8 months and consisted of the following components: (1) monthly updated feedback on 1-year revision, 30-day readmission, 30-day complications, long (upper quartile) LOS and these four indicators combined in a composite outcome; (2) interactive education; (3) an action toolbox including evidence-based quality improvement initiatives (QIIs) to facilitate improvement of above indicators; and (4) bimonthly surveys to report on QII undertaken.

Main outcome measures The primary outcome was textbook outcome (TO), an all-or-none composite representing the best outcome on all performance indicators (ie, the absence of revision, readmissions, complications and long LOS). The individual indicators were analysed as secondary outcomes. Changes in outcomes from pre-intervention to intervention period were compared between intervention versus control hospitals, adjusted for case-mix and clustering of patients within hospitals using random effect binary logistic regression models. The same analyses were conducted for intervention hospitals that did and did not introduce QII.

Results 16 314 patients were analysed in intervention hospitals (12 475 before and 3 839 during intervention) versus 16 609 in control hospitals (12 853 versus 3 756). After the intervention period, the absolute probability to achieve TO increased by 4.32% (95% confidence

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Given the increasing number of total hip and knee arthroplasties (THA and TKA) performed worldwide, the number of adverse events and revision surgeries are expected to increase as well as societal costs. High-quality care may reduce the risk of adverse events and improve efficiency by avoiding unnecessarily long length of stays (LOS).

WHAT THIS STUDY ADDS

⇒ A multifaceted quality improvement intervention including frequent feedback on performance, interactive education combined with an action implementation toolbox containing evidenced-based quality improvement initiatives (QIIs) was effective to improve patient outcomes after THA and TKA.

⇒ The absolute probability of patients achieving textbook outcome (TO) (ie, absence of revision, readmission, complications and LOS) increased by 4.32% (95% CI 4.30% to 4.34%) more in intervention hospitals than control hospitals, with effect size depending on QII introduced.

⇒ Intervention hospitals particularly improved more in reducing patients with long LOS.

interval (CI) 4.30–4.34) more in intervention than control hospitals, corresponding to 21.6 (95% CI 21.5–21.8), i.e., 22 patients treated in intervention hospitals to achieve

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ These findings support that frequent feedback to surgical teams should be supplemented by interactive education and facilitated by evidence-based improvement initiatives tailored to specific outcomes, to further improve the quality of delivered patient care in arthroplasty surgery.

one additional patient with TO. Intervention hospitals had a larger increase in patients achieving TO (ratio of adjusted odds ratios 1.24, 95%CI 1.05-1.48) than control hospitals, a larger reduction in patients with long LOS (0.74, 95%CI 0.61-0.90) but also a larger increase in patients with reported 30-day complications (1.34, 95%CI 1.00-1.78). Intervention hospitals that introduced QII increased more in TO (1.32, 95%CI 1.10-1.57) than control hospitals, with no effect shown for hospitals not introducing QII (0.93, 95%CI 0.67-1.30).

Conclusion The multifaceted QI intervention including monthly feedback, education, and a toolbox to facilitate QII effectively improved patients achieving TO. The effect size was associated with the introduction of (evidence-based) QII, considered as the causal link to achieve better patient outcomes.

Trial registration number NCT04055103.

INTRODUCTION

Total hip and knee arthroplasties (THA and TKA) are frequently used cost-effective treatments for symptomatic osteoarthritis and end-stage rheumatoid arthritis to reduce pain and improve patients' functionality.¹⁻³ Due to the increasing number of procedures, the absolute number of adverse events and costly revision surgeries are likely to increase if the risk remains the same.⁴⁻⁷ Several studies and arthroplasty reports have shown considerable between-hospital variation in revision, readmission, complications and length of stay (LOS) for both THA and TKA, indicating huge improvement potential.⁷⁻¹⁷

In recent years, arthroplasty registries have provided surgeons and hospitals with audit and feedback (A&F) on their performance, aiming to improve the quality of care delivered.^{7 11-18} A Cochrane review showed A&F to be effective with a median absolute improvement of 4.3% (IQR 0.5% to 16%).¹⁹ Worldwide, arthroplasty registries include different performance indicators in their feedback, with revision most commonly used.^{7 11-18} A recent study showed that Dutch orthopaedic surgeons would like to receive feedback not just on revisions but also on readmission, complications and LOS.²⁰ For arthroplasty surgery, even a relatively small absolute improvement will have huge impact considering the large annual number of THA and TKA performed worldwide. Studies have shown that A&F maybe more effective when for example, an action implementation toolbox is added to facilitate actions undertaken instead of a 'passive' single element (feedback or education alone).^{19 21-23} However, a previous study including such an action implementation toolbox only showed improvement in process

indicators whereas the ultimate goal is to improve patient outcomes.²³ In addition, A&F seems to be more effective when feedback is delivered by a senior colleague, at least monthly, in both verbal and written format and when explicit goals and specific actions are planned.¹⁹

We aimed to evaluate the effect of a prospective multifaceted A&F intervention on a composite of clinical outcomes (including 1-year revision, 30-day readmission, 30-day complications and long LOS) for patients undergoing THA and TKA.

METHODS

Study design and participants

A cluster randomised controlled trial (RCT) was nested in the nationwide Dutch Arthroplasty Register (LROI), including 20 hospitals performing THA and TKA across the Netherlands. During the 21 months pre-intervention period (from 1 January 2018 to 30 September 2019), all 20 hospitals established a data linkage between the registry and hospital data, and the research group developed the feedback and action implementation toolbox. Participating orthopaedic departments were then randomised into 10 intervention and 10 control hospitals. The intervention was applied over an 8 months' period (1 October 2019–31 May 2020) (figure 1). Control hospitals continued with usual care. We compared the change in patient outcomes from the pre-intervention to the end of the intervention period between intervention and control hospitals as the effect attributable to introduction of the intervention. The trial was pre-registered (ClinicalTrials.gov, NCT04055103) and the LUMC Medical Ethical Committee waived the need for ethical approval under Dutch law (CME, G18.140).²⁴ The study was announced on the website of the Dutch Orthopaedic Association and the first 20 orthopaedic departments agreeing to participate in the study were included. All THA and TKA procedures performed in the 20 departments were included. No exclusion criteria were used.

COVID-19

We originally planned to include a 'sustainability phase' after 6 months, where intervention hospitals would no longer be actively supported and the control hospitals would receive the intervention (ClinicalTrials.gov, NCT04055103).²⁴ This planned sustainability phase was delayed by 2 months so that the intervention period ended May 2020 rather than the planned March 2020 to maintain sufficient statistical power, given the reduction in elective care caused by the COVID-19 outbreak in early March 2020. The number of procedures decreased to 625, 54 and 545 in March, April and May 2020, respectively, compared with an average 1215 THA and TKA per month in 2018–2019. In addition, we had planned to match hospitals as part of the intervention to exchange

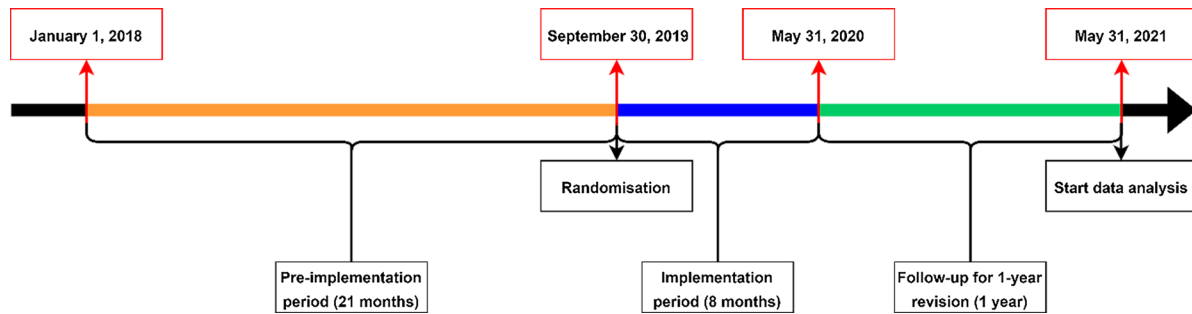


Figure 1 Study period;

information on best practices and identify areas for improvement, which could not be implemented due to government-imposed COVID-19 restrictions.²⁴

Randomisation and masking

Randomisation was stratified by hospital type to achieve an equal distribution of academic, teaching, non-teaching and private hospitals, as these generally differ in size and are therefore likely to differ in available IT and quality improvement (QI) capacity. Participating hospitals were categorised within one of four groups and then allocated in a 1:1 ratio to the intervention or control group. Due to the nature of the intervention, orthopaedic surgeons of intervention hospitals could not be masked but patients were masked to study group allocation. By liaising with hospital IT specialists to extract hospital data on readmissions, complications and LOS, we tried to minimise potential bias as they were masked to study group allocation. In all intervention hospitals, the head of the orthopaedic department was appointed as contact person and acted as ‘clinical champion’.

Intervention

The intervention was designed based on evidence regarding effective feedback^{19 21–23} for orthopaedic surgeons²⁰ and included the following components:

1. Monthly updated feedback was (securely) emailed individually to all orthopaedic surgeons performing THA and TKA in the intervention hospitals. Feedback included case-mix-adjusted indicator outcomes graphically presented in funnel plots and CUSUM charts.²⁵ The following indicators were reported: 1-year revision (including reasons for revision to align with quality improvement initiatives (QIIs), that is, infection, dislocation (only THA), prosthesis loosening, and technical failure (only TKA),⁸ 30-day readmission, 30-day complications, long (upper quartile) LOS and a composite outcome including all above mentioned indicators. A brief description to interpret the findings for each indicator was provided below each graph tailored to that specific hospital (online supplemental appendix I).
2. Education to interpret the feedback was provided by PvS (medical doctor) in the first month of the intervention period, combined with clear targets for improvement of

specific indicators. Orthopaedic surgeons learnt how to interpret funnel plots and CUSUM charts, and how to use these charts for QI. This was based on a previous survey showing this represented a knowledge gap so that education should be part of the intervention.^{20 21} As a reference, a video (online supplemental appendix II) and a pocket card (online supplemental appendix III) were available to summarise the educational meeting.

3. An action implementation toolbox including evidence-based QII for each indicator reported in the feedback, to facilitate taking actions to improve care, based on scientific literature, expert opinion and guidelines. The plan-do-study-act (PDSA) cycle was added to help surgeons design local QI projects (online supplemental appendix IV).
4. A short survey was emailed every 2 months together with the feedback to evaluate adherence to the intervention, encourage reviewing the feedback, verify which QII were introduced, and stimulate trial engagement. Participants could report best practices and experiences to be added to the toolbox and shared with others, also to stimulate trial engagement (online supplemental appendix V).

Control hospitals continued with usual care, meaning that no specific intervention was implemented. This means that orthopaedic surgeons have access to the password-protected LROI-dashboard where overall between-hospital variation in revision could be viewed in real time, as well as averages for patient characteristics and patient-reported outcome measures. However, it requires logging in to look up the information, rather than receiving it through email, and gives no comparative information on readmission, complications and long LOS (or the composite). Since 2015, all surgeons in both control and intervention hospitals have had access to the LROI dashboard, however, a recent study showed that 39% of the orthopaedic surgeons did not interpret funnel plot correctly, and 34% never logged in.²⁰

Graphical displays of performance

Funnel plots are already used in the LROI dashboard as a graphical aid to show between-hospital variation in revisions, adjusted for case-mix. Hospitals plotted between the control limits (2 SD) perform as expected given their case-mix, while hospitals plotted above or

under the control limit perform significantly worse or better, respectively.

A CUSUM chart was added to the monthly feedback since it shows patient level rather than aggregated performance data during a time period. For every consecutive patient, the observed minus expected probability for an event is plotted. When the score goes up, the observed performance is worse than expected, and vice versa when going down. A signal (alert) was generated when crossing the 5.0 control limit meaning that hospital performance was 'out-of-control' for the quality indicator, after which the chart was reset to zero. When no signal is generated a hospital is 'in-control'.²⁶ The level of the control limit determines the trade-off between the number of false-positive and false-negative signals. We showed previously that the CUSUM chart with a 5.0 control limit enabled earlier detection of worsening performance for 1-year revisions with good accuracy compared with the funnel plot, thereby allowing initiatives to start earlier.²⁵

Outcome evaluation

The primary outcome was the textbook outcome (TO) composite, with the individual outcomes included in TO analysed as secondary outcomes. The TO composite is an all-or-none concept representing the best outcome on commonly used indicators for THA and TKA (ie, the absence of 1-year revision, 30-day readmission, 30-day complications and long LOS). The 1-year revision was calculated based on primary and revision surgery dates, with all patients having at least 1-year follow-up, as routinely collected in the LROI. By including revisions in the composite, a 1-year follow-up was needed after the implementation period to calculate TO (figure 1). Other outcomes were calculated based on the index hospitalisation in which the primary THA or TKA was performed. Outcomes were defined as follows:

- ▶ Revision: Exchange, removal or addition of any component within 1 year after the primary surgery.
- ▶ Readmission: Any admission within 30 days after discharge of the index hospitalisation to the same hospital.
- ▶ Complication: Any complication other than revision during the index hospitalisation or within 30 days after discharge, using the nationwide definition of a complication.²⁷
- ▶ Long LOS: LOS of the index hospitalisation longer than the 75th percentile (upper quartile), based on all patients treated, to take into account possible between-hospital differences in sensitivity to report complications.²⁸

Data collection

Routinely submitted LROI data regarding revisions and patient characteristics were used, supplemented with hospital data on readmission, complications and LOS for all patients. LROI data were linked to hospital data by an IT specialist from each hospital to ensure

anonymous data exchange. LROI data completeness is checked annually against Hospital Electronic Health Records and currently exceeds 99% for primary procedures, and 97% for revisions.^{29 30} The LROI uses barcode scanning to enable tracing of prosthetic components so revisions performed in another hospital are included. The following patient-level LROI data were provided: whether a revision had taken place, reason for revision and the patient characteristics age at surgery, gender, body mass index (kg/m²), current smoking status (yes/no), American Society of Anaesthesiologists (ASA) classification (I-IV) and diagnosis (osteoarthritis/non-osteoarthritis). Collected data were locked prior to the analyses.

Statistical analysis

At least 18 participating hospitals (9 per arm) were needed to detect a difference in TO of 70% vs 80% with 80% power, α of 0.05, a median of 100 procedures per hospital, and assuming an intra-hospital correlation of 0.02. We included 20 hospitals (10 per arm) in case hospitals would drop out. To assess whether participating hospitals were a representative selection, we compared the median number of procedures and median percentage of revisions for both THA and TKA during the study period in participating centres versus all other Dutch centres, using a Mann-Whitney U test.

Patient characteristics were missing in less than 2% of patients. These were considered missing at random and imputed using multiple imputations for 10 rounds with predictive mean matching as the underlying model. All patient characteristics and outcomes (ie, TO, revision, readmission, complications and long LOS) were used as predictors, but only patient characteristics were imputed.

Data were analysed following an intention-to-treat approach, classifying hospitals in study groups as randomised. Random effects binary logistic regression models were used to estimate the impact of the intervention on TO as the primary outcome and each secondary outcome, while accounting for patient clustering within hospitals. All models were adjusted for all measured patient characteristics. Outcomes between pre-intervention and intervention period were first compared within intervention and control hospitals, expressed as adjusted ORs. The change in outcomes from pre-intervention period was then compared between intervention and control hospitals by including an interaction term between study group and period, and quantified as the ratio of adjusted ORs with corresponding 95% CIs. We calculated the number of patients needed to be treated during the intervention period to achieve one additional patient with TO in intervention hospitals as one divided by the absolute risk difference. The absolute difference in TO probability was derived from the estimated parameters obtained by the above logistic regression

models using a marginal standardisation method.³¹ Corresponding 95% CIs were computed from non-parametric bootstrapping based on 2000 replications. The same analyses were performed to compare intervention hospitals introducing QII and intervention hospitals not introducing QII, versus control hospitals. These analyses were conducted from the rationale that these QIIs were the causal link to achieve improved patient outcomes, which would thereby support intervention efficacy. Information on QII introduced was taken from the process evaluation (see below). All analyses were conducted for all patients, and separately for patients with THA and TKA, given the known difference in revisions and complication risks and that a difference in baseline risk may affect the absolute risk reduction achieved.^{7–17 32}

All *p* values were two-sided and values below 0.05 were considered statistically significant in all analyses. Analyses were performed using STATA (V.14; StataCorp).

Process evaluation and intervention fidelity

Surveys were sent by email in November 2019, January 2020 and March 2020 and compiled using Qualtrics (online supplemental appendix V). As surveys were sent together with the feedback, response also indicated the email was read and feedback received. Questions were asked to evaluate adherence to intervention components and therefore included whether orthopaedic surgeons could interpret the feedback and what other information or tools were needed for further improvement. In addition, we asked which QIIs were undertaken as ultimately the feedback was intended to initiate actions, including whether these QIIs were based on the toolbox or other evidence. Descriptive statistics were used to explore the number of QII per intervention hospital and the source of the initiatives.

Patient and public involvement

Patients or the public were not involved in the design of the study.

RESULTS

Of the 33 205 patients who underwent THA or TKA in the 20 participating hospitals during the pre-intervention and intervention period, 282 had missing data for TO, leaving 32 923 (99.2%) patients eligible for analysis. Of these, 16 314 patients were analysed in the intervention hospitals (12 475 before and 3839 during the intervention period) vs 16 609 in control hospitals (12 853 vs 3756). Participating hospitals were comparable to all other Dutch hospitals in distribution of type of hospital, median revision rate (1.7% vs 1.7% for THA, *p*=1.00% and 1.4% versus 0.9% for TKA, *p*=0.62) and median number of THA surgeries (930 vs 699; *p*=0.21) but had higher median number of TKA surgeries (700 vs 582; *p*<0.05) (figure 2).

Table 1 shows that hospital and patient characteristics were comparable between intervention and control hospitals, except for slightly more smokers and fewer ASA III-IV patients in intervention hospitals. During the study period, 28 108 patients achieved TO (85.4%), 529 (1.6%) underwent a revision within 1 year, 1218 (3.7%) had a readmission within 30 days, 1214 (3.7%) experienced a complication within 30 days and 3662 (11.1%) had a long LOS, with considerable between-hospital variation in all outcomes (shown by the IQR in table 1) in both intervention and control hospitals. LOS was not normally distributed, making it challenging to create equal quartiles so that the closest integer value was chosen. This resulted in above 4 days defined as long LOS for both THA and TKA, and explains that the median percentage of patients with long LOS is considerably smaller than 25%.

Outcome evaluation

Table 2 shows changes in clinical outcomes from the pre-intervention to intervention period for both intervention and control hospitals. Intervention hospitals significantly improved in achieving more patients with TO over time for THA/TKA combined (adjusted OR 1.39, 95% CI 1.23 to 1.58), as did control hospitals (adjusted OR 1.14, 95% CI 1.02 to 1.48). Even though intervention hospitals had better pre-intervention TO performance, that is, potentially less room for improvement, they improved significantly more than control hospitals (ratio of adjusted ORs 1.24, 95% CI 1.05 to 1.48). The effect was also significant for THA alone (1.34, 95% CI 1.06 to 1.69), but not for TKA (1.12, 95% CI 0.87 to 1.44), although it went in the same direction. For the secondary outcomes, intervention hospitals also showed a significantly higher reduction in the percentage of patients with long LOS than control hospitals for THA/TKA combined and THA. The same trend was observed for 30-day readmission for THA, although non-significant. The percentage of patients with reported 30-day complications increased more in intervention than control hospitals for THA/TKA combined but not for THA or TKA separately. No significant effects were found for revisions.

The absolute probability of TO increased by 4.32% (95% CI 4.30% to 4.34%) more in intervention hospitals than control hospitals, corresponding to 21.6 (21.5 to 21.8), that is, 22 patients treated in intervention hospitals to achieve one additional patient with TO.

Process evaluation and intervention fidelity

The education meetings were scheduled such that all orthopaedic surgeons could attend (unless still in surgery). Each meeting ended by discussing which performance indicators would be the focus of improvement initiatives and which specific actions would be taken. Two orthopaedic surgeons were absent during this interactive education session in 3 intervention

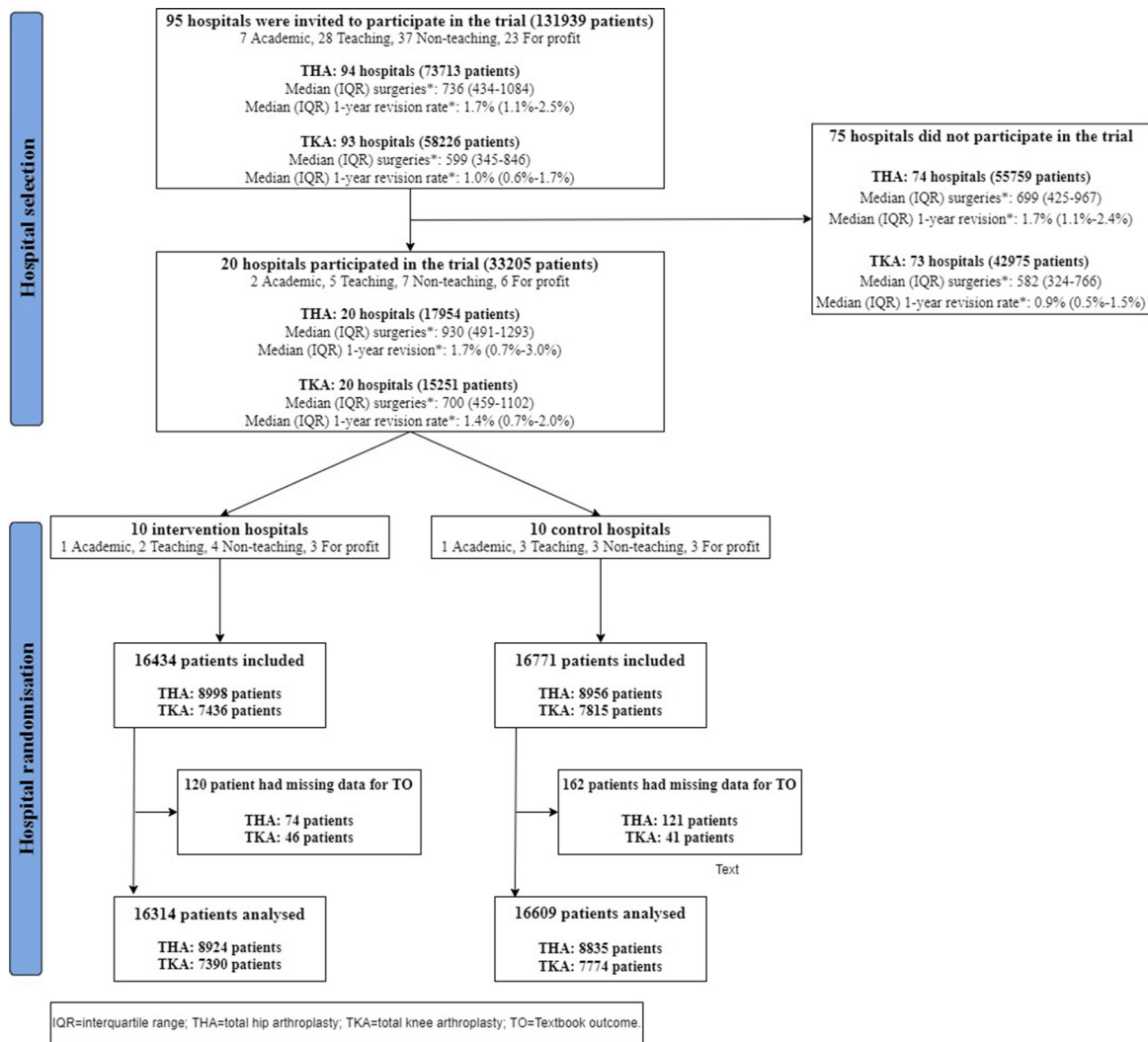


Figure 2 Trial profile. THA, total hip arthroplasty; TKA, total knee arthroplasty.

hospitals and 1 surgeon in 3 hospitals, meaning that 52 of the total of 61 orthopaedic surgeons (85%) attended. From all surgeons, 45 (74%) completed the first survey, 39 (64%) the second survey and 35 (57%) the third survey. Fifty-five surgeons (90%) completed the survey at least once, meaning that the feedback was reviewed by at least 90% of the surgeons since it was sent together with the survey. Twenty-three (38%) orthopaedic surgeons completed the survey at all time points, and at least one surgeon for each hospital. In addition, 91% of respondents reported the feedback was clear after receiving the education. In terms of trial engagement, four hospitals reported they needed additional educational explanations on funnel plots and CUSUM charts, and two hospitals would appreciate more QIIs included in the toolbox. In addition, seven hospitals requested being linked to a hospital that scored better on a performance indicator to improve further ('learning from the best').

Table 3 shows descriptions of QIIs introduced in each hospital, intended to improve patient outcomes, including whether these were taken from the toolbox

or based on other evidence. The median number of performance indicators for which QII were undertaken per hospital was 2 (IQR 1–2). Two hospitals did not introduce any QII, and of the remaining eight hospitals most introduced QII to improve LOS.

Intervention hospitals that introduced QIIs improved significantly more in TO than control hospitals (1.32, 95% CI 1.10 to 1.57), whereas intervention hospitals not introducing any QII showed similar changes as control hospitals (0.93, 95% CI 0.67 to 1.30) (figure 3). Of note, pre-intervention TO on average was lower for intervention hospitals that introduced QII compared with hospitals not introducing QII (85.2% vs 94.5%, $p < 0.01$) with control hospitals at 82.6%. For the secondary outcomes, intervention hospitals that introduced QII to reduce long LOS improved significantly more than control hospitals. For complications, no difference was found for intervention hospitals that introduced QII targeting complications but hospitals not introducing these QII increased more in complications than control hospitals. No significant differences were found

Table 1 Hospital and patient characteristics by hospital group during the study period (from 1 January 2018 to 31 May 2020)

Hospital characteristics	All hospitals (n=20)			Intervention hospitals (n=10)			Control hospitals (n=10)		
	All surgeries	THA	TKA	All surgeries	THA	TKA	All surgeries	THA	TKA
Geographical region									
Northwest	3 (15)	1 (10)		1 (10)			1 (10)		
Northeast	4 (20)	2 (20)		2 (20)			2 (20)		
Southwest	6 (30)	3 (30)		3 (30)			3 (30)		
Southeast	5 (25)	3 (30)		3 (30)			3 (30)		
Central area	2 (10)	1 (10)		1 (10)			2 (20)		
Status									
Academic	2 (10)	1 (10)		1 (10)			1 (10)		
Teaching	5 (25)	2 (20)		2 (20)			3 (30)		
Non-teaching	7 (35)	4 (40)		4 (40)			3 (30)		
For-profit	6 (30)	3 (30)		3 (30)			3 (30)		
Median (IQR) number of surgeons*	6 (5–7)			6 (5–7)			7 (5–9)		
All surgeries	1472 (1059–2371)	920 (487–1292)	667 (454–1098)	1472 (1350–2152)	920 (723–1133)	612 (388–1041)	1452 (766–2525)	772 (257–1473)	728 (605–1177)
Median (IQR) number of surgeries in study period*									
Indicator outcomes:									
Median (IQR) TO (%)*	85.1 (77.0–95.6)	84.4 (75.9–95.6)	84.5 (77.1–95.7)	87.0 (75.0–96.6)	86.9 (76.8–96.9)	84.5 (72.2–95.5)	85.0 (77.2–95.0)	83.6 (71.8–94.1)	85.0 (79.9–96.1)
Median (IQR) revision (%)*	1.4 (0.8–2.6)	1.7 (0.7–3.0)	1.3 (0.7–2.0)	1.6 (0.8–3.0)	1.7 (0.6–3.2)	1.7 (0.8–2.2)	1.3 (0.9–2.3)	1.8 (0.8–3.1)	0.9 (0.7–1.8)
Median (IQR) readmission (%)*	4.4 (1.6–5.0)	4.3 (1.8–5.1)	4.0 (1.6–5.2)	4.6 (1.2–4.9)	4.0 (1.1–5.4)	4.7 (2.5–5.4)	4.2 (1.8–5.1)	4.3 (2.2–5.1)	3.6 (1.4–5.2)
Median (IQR) complications (%)*	3.0 (1.9–4.5)	3.6 (2.1–5.9)	2.5 (1.3–3.7)	2.2 (1.5–3.9)	2.8 (1.6–4.7)	2.3 (1.2–3.9)	3.3 (2.9–6.1)	4.1 (3.2–7.6)	2.8 (1.0–4.6)
Median (IQR) Long LOS (%)*	10.9 (2.1–19.7)	10.3 (2.1–19.3)	9.9 (2.1–19.4)	8.6 (2.0–20.7)	9.3 (2.1–19.0)	9.5 (1.7–23.3)	11.4 (1.5–19.6)	10.9 (1.4–25.0)	11.8 (2.1–17.1)
All surgeries	(n=32923)	THA (n=17759)	TKA (n=15164)	All surgeries (n=16314)	THA (n=8924)	TKA (n=7390)	All surgeries (n=16609)	THA (n=8835)	TKA (n=7774)
Mean (SD) age (years)	68.5 (9.6)	68.5 (10.3)	68.4 (8.7)	68.1 (9.6)	67.9 (10.3)	68.3 (8.6)	68.9 (9.5)	69.1 (10.2)	68.6 (8.7)
Gender, female	20656 (62.7)	11323 (63.8)	9333 (61.5)	10233 (62.7)	5670 (63.5)	4563 (61.7)	10423 (62.8)	5653 (64.0)	4770 (61.4)
Mean (SD) BMI (kg/m ²)	28.1 (4.8)	27.0 (4.5)	29.4 (4.8)	28.0 (4.8)	26.9 (4.4)	29.3 (4.8)	28.3 (4.8)	27.2 (4.5)	29.5 (4.9)
Smoking	3068 (9.3)	1830 (10.3)	1238 (8.2)	1595 (9.8)	964 (10.8)	631 (8.5)	1473 (8.9)	866 (9.8)	607 (7.8)
ASA classification									
ASA I	5158 (15.7)	3204 (18.0)	1954 (12.9)	2807 (17.2)	1812 (20.3)	995 (13.5)	2351 (14.2)	1392 (15.8)	959 (12.3)
ASA II	21083 (64.1)	11029 (62.1)	10054 (66.3)	10444 (64.0)	5528 (62.0)	4916 (66.5)	10639 (64.1)	5501 (62.3)	5138 (66.1)
ASA III-IV	6673 (20.3)	3521 (19.8)	3152 (20.8)	3057 (18.7)	1581 (17.7)	1476 (20.0)	3616 (21.8)	1940 (22.0)	1676 (21.6)
Diagnosis									
Osteoarthritis	30258 (93.7)	15643 (89.8)	14615 (98.2)	15012 (93.7)	7899 (90.2)	7113 (97.9)	15246 (93.6)	7744 (89.4)	7502 (98.4)
Non-osteoarthritis	2051 (6.3)	1780 (10.2)	271 (1.8)	1011 (6.3)	859 (9.8)	152 (2.1)	1040 (6.4)	921 (10.6)	119 (1.6)

Values are numbers (percentages) unless stated otherwise. Data relative to the pre-implementation and implementation period were pooled in intervention and control hospitals. Percentages for ASA classifications might not sum to 100 because of roundings.
 *The value under 'Median (IQR)' indicates percentage of the median hospital.
 ASA, American Society of Anaesthesiologists; BMI, body mass index; LOS, length of stay; SD, SD deviation; THA, total hip arthroplasty; TKA, total knee arthroplasty; TO, Textbook Outcome.

Table 2 Comparison of primary and secondary outcomes by study group (ie, intervention or control hospitals) between pre-implementation and implementation period

Surgical outcomes	Intervention hospitals				Control hospitals				Intervention vs control hospitals		
	Pre-implementation	Implementation	Implementation vs pre-implementation adjusted OR (95% CI)	Pre-implementation	Implementation	Implementation vs pre-implementation adjusted OR (95% CI)	Ratio of adjusted ORs (95% CI)	P value	ICC		
All surgeries (n=32 923)											
Textbook outcome*	10 930 (87.6)	3421 (89.1)	1.39 (1.23 to 1.58)	10 615 (82.6)	3142 (83.7)	1.14 (1.02 to 1.27)	1.24 (1.05 to 1.48)	0.011	0.299		
1-year revision	199 (1.6)	61 (1.6)	0.93 (0.69 to 1.24)	202 (1.6)	67 (1.8)	1.12 (0.85 to 1.48)	0.82 (0.55 to 1.23)	0.341	0.074		
30-day readmission	399 (3.2)	118 (3.1)	0.89 (0.72 to 1.10)	547 (4.3)	154 (4.1)	0.95 (0.79 to 1.14)	0.95 (0.71 to 1.25)	0.697	0.108		
30-day complications	303 (2.4)	112 (2.9)	1.12 (0.90 to 1.40)	638 (5.0)	161 (4.3)	0.85 (0.71 to 1.01)	1.34 (1.00 to 1.78)	0.046	0.208		
Long LOS	1154 (9.3)	302 (7.9)	0.67 (0.57 to 0.77)	1731 (13.5)	475 (12.6)	0.85 (0.71 to 1.01)	0.74 (0.61 to 0.90)	0.002	0.533		
Total hip arthroplasty (n=17 759)											
Textbook outcome*	6015 (88.0)	1863 (89.3)	1.39 (1.17 to 1.67)	5533 (80.9)	1611 (80.8)	1.06 (0.92 to 1.23)	1.34 (1.06 to 1.69)	0.013	0.303		
1-year revision	112 (1.6)	36 (1.7)	0.98 (0.69 to 1.43)	130 (1.9)	44 (2.2)	1.13 (0.80 to 1.60)	0.86 (0.51 to 1.30)	0.572	0.104		
30-day readmission	224 (3.3)	61 (2.9)	0.82 (0.61 to 1.10)	295 (4.3)	104 (5.2)	1.20 (0.95 to 1.51)	0.69 (0.48 to 1.00)	0.051	0.105		
30-day complications	194 (2.8)	72 (3.4)	1.12 (0.85 to 1.49)	390 (5.7)	106 (5.3)	0.90 (0.72 to 1.13)	1.25 (0.87 to 1.80)	0.218	0.219		
Long LOS	616 (9.0)	164 (7.9)	0.66 (0.54 to 0.82)	1025 (15.0)	296 (14.8)	0.91 (0.77 to 1.07)	0.70 (0.54 to 0.92)	0.01	0.531		
PROMs response rate											
Total knee arthroplasty (n=15 164)											
Textbook outcome*	4915 (87.2)	1558 (88.9)	1.39 (1.16 to 1.67)	5082 (84.5)	1531 (86.9)	1.25 (1.05 to 1.48)	1.12 (0.87 to 1.44)	0.371	0.333		
1-year revision	87 (1.5)	25 (1.4)	0.89 (0.57 to 1.40)	72 (1.2)	23 (1.3)	1.11 (0.69 to 1.79)	0.80 (0.41 to 1.53)	0.492	0.053		
30-day readmission	175 (3.1)	57 (3.3)	0.98 (0.72 to 1.33)	252 (4.2)	50 (2.8)	0.65 (0.48 to 0.89)	1.50 (0.97 to 2.32)	0.071	0.095		
30-day complications	109 (1.9)	40 (2.3)	1.13 (0.78 to 1.65)	248 (4.1)	55 (3.1)	0.75 (0.57 to 1.01)	1.52 (0.94 to 2.46)	0.085	0.204		
Long LOS	538 (9.5)	138 (7.9)	0.66 (0.53 to 0.82)	706 (11.7)	179 (10.2)	0.83 (0.68 to 1.00)	0.79 (0.59 to 1.06)	0.115	0.515		
PROMs response rate											

Values are numbers (percentages) unless stated otherwise. ORs were estimated using random effect binary logistic regression models to compare surgical outcomes between pre-implementation and implementation periods in intervention and control hospitals. The ratio of adjusted ORs captured the effect of the intervention by comparing the change in outcomes from the pre-implementation to implementation periods between the intervention and control hospitals based on the interaction term. A ratio of adjusted OR value above 1 for the textbook outcome indicates improvement in the intervention vs control hospitals and a value below one deterioration. In contrast, a ratio of adjusted OR value below 1 for 1-year revision, 30-day readmission, 30-day complications and long LOS indicates improvement and a value below 1 deterioration. Estimates and 95% CI considered clustering of patients at the hospital level. All outcomes were adjusted for gender, age, body mass index, smoking, American Society of Anesthesiologists score and diagnosis (osteoarthritis vs non-osteoarthritis).

*Composite of an all-or-none concept with the best outcome on all performance indicators (ie, 1-year revision, 30-day readmission, 30-day complications and long LOS).
ICC, intraclass correlation; LOS, length of stay; PROMs, patient-reported outcome measures.

Table 3 Quality improvement initiatives per hospital and the source of the initiatives

Intervention hospital	Quality improvement initiatives	Toolbox	Literature	Expert opinion
1	<i>LOS:</i>			
	Discharge 1 day postoperative if possible.	No	Yes	No
2	<i>Revision:</i>			
	Reduce the number of dislocations for THA by no longer placing a 28 mm cup and placing an 'Avantage' cup earlier in older patients.	Yes	Yes	Yes
	Pairing surgeons with more dislocations with surgeons with few dislocations to learn from best practices.	No	Yes	Yes
	<i>LOS:</i>			
	Start mobilising earlier after surgery.	No	No	No
	Improve patient expectation management.	No	Yes	No
	Earlier consultation of transfer agency.	No	Yes	No
3	<i>Readmission and complications:</i>			
	Reduce wound leakage and surgical site infections by adjusting the wound closure technique, tissue protector for THA, and tranexamic acid during wound closure for TKA.	No	Yes	Yes
4	<i>LOS:</i>			
	Earlier consultation of transfer agency.	No	No	Yes
5	<i>Revision, readmission and complications:</i>			
	Reduce surgical site infections and prosthetic joint infections by adjusting the wound closure technique.	No	Yes	Yes
	Covering the sterile surgical field differently.	No	No	Yes
	Short-term use of the tourniquet for TKA.	No	No	Yes
	Use of prophylactic antibiotic as suggested in de guidelines of the Netherlands Orthopaedic association.	No	Yes	No
6	<i>Revision:</i>			
	Reduce the number of infections by adopting preoperative, intraoperative and postoperative interventions from the toolbox and the literature (not defined).	Yes	Yes	No
	<i>LOS:</i>			
	Earlier consultation of transfer agency.	Yes	Yes	No
7	<i>LOS:</i>			
	Mobilising on the day of surgery.	Yes	No	No
	Inform the patient before surgery about the expected LOS.	Yes	No	No
8	<i>Revision:</i>			
	Introduction of a new type of prosthesis.	No	Yes	Yes
	Introduction of an infection discussion in which improvement initiatives are evaluated.	No	Yes	No
	<i>LOS:</i>			
	Prevent wound leakage by keeping the compression bandage in place longer in patients who have had surgery late in the day.	No	No	Yes
	Closing the fascia with polydioxanone suture.	No	No	Yes
	Close the subcutis in two layers.	No	No	Yes
	Improve patient flow to the care hotel.	No	No	Yes

These are the quality improvement initiatives as reported in the bimonthly surveys by the orthopaedic surgeons in the intervention hospitals. The initiatives are described under the indicator that the hospital aimed to improve with the initiative. However, the quality initiatives mentioned could affect other indicators, both positively and negatively. Two hospitals did not introduce any initiatives and are not included in the table. LOS, length of stay; THA, total hip arthroplasty; TKA, total knee arthroplasty.

for hospitals introducing QII to reduce revisions or readmissions.

DISCUSSION

The present study has shown that the multifaceted QI intervention was effective to increase the percentage of patients achieving TO more in

intervention than control hospitals. Intervention hospitals that introduced QII improved significantly more in performance on TO than control hospitals, whereas intervention hospitals not introducing any QII showed comparable changes as control hospitals (but had higher pre-implementation TO). For the secondary outcomes, a higher reduction in

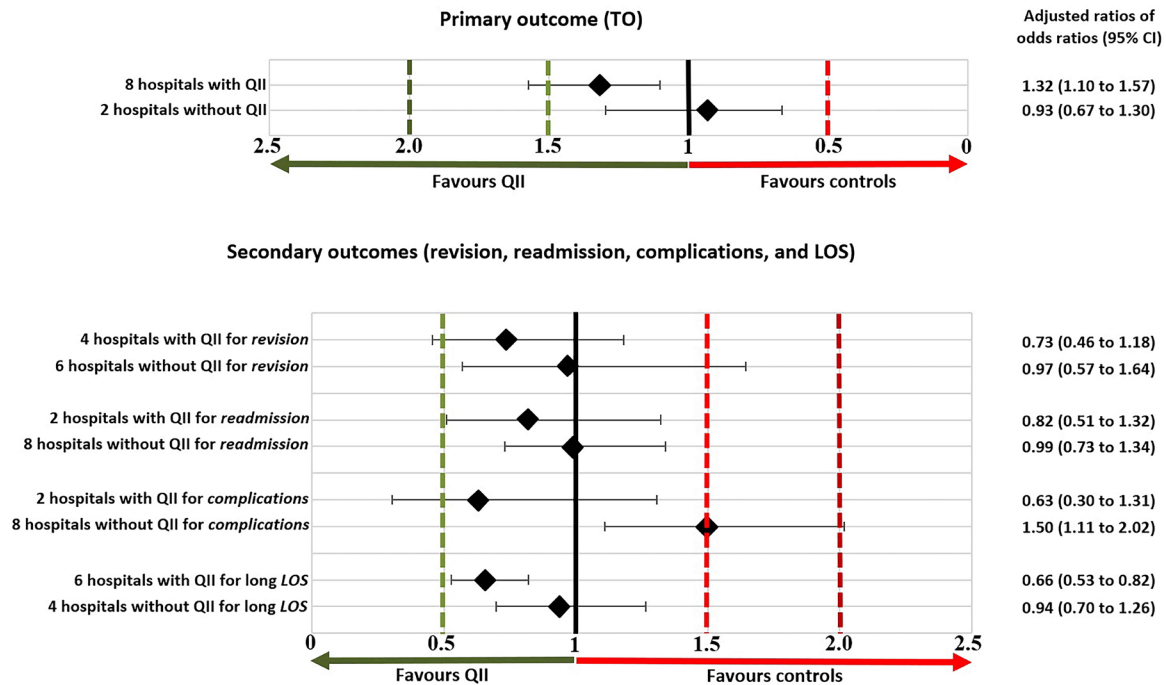


Figure 3 Primary and secondary outcomes by the implementation of quality improvement initiatives. LOS, length of stay; TO, textbook outcome.

patients with long LOS was found for intervention than control hospitals, and hospitals introducing QII to reduce LOS improved significantly more than control hospitals whereas hospitals not introducing these QIIs showed similar changes. Effects for readmission and revision seemed to go in the same direction, but were non-significant. However, intervention hospitals also showed a higher increase in the percentage of patients with reported complications than control hospitals. This seemed to be due to hospitals not introducing QII targeting complications, as those hospitals showed a higher increase in reported complications than control hospitals whereas hospitals introducing QIIs targeting complications showed similar changes. In addition, it may reflect increased sensitivity in reporting complications associated with the intervention. Taken together, these findings suggest that our multifaceted QI intervention was effective to improve TO for patients with THA/TKA, most likely through the introduction of targeted QII particularly reducing long LOS.

Although a significant effect was only found for THA, the direction of the effect and some secondary outcomes (eg, long LOS) were similar for TKA. This may be due to the smaller volume, as the median number of TKA surgeries was considerably smaller than for THA in intervention hospitals (table 1), which may explain why the effect went in the same direction but was not significant. In addition, the baseline risks for revisions and complications were lower for TKA, mostly associated with smaller absolute risk reductions.

Comparison to the literature

The present study showed an absolute larger improvement of 4.32% in intervention versus control hospitals, similar to the median improvement shown for A&F interventions in a Cochrane review including 140 studies.¹⁹ This suggests that about 50% of included studies in that review had smaller effects than the present study. A comparable cluster RCT using control charts and regular feedback resulted in an absolute reduction of major adverse events of 0.9%, or 114 patients needed to treat in intervention hospitals to prevent one adverse event.³³ However, such comparisons need to be done cautiously as included studies involve different populations being targeted and different control groups. For interventions like statins and aspirin, it is known that both the absolute reduction and the number needed to treat (NNT) depend on the baseline risk.³² This is equally relevant in our study, as the baseline risk for particularly revision and complications are already low, meaning that absolute risk reductions tend to be lower. This likely explains why the overall effect is driven by LOS and readmissions, with higher baseline risk.

Other QI initiatives have been described within orthopaedics, such as the Continuous Quality Improvement Programme for hip and knee replacement surgical care Canada.³⁴ A standardised care pathway was developed guided by the Triple Aim framework and six quality dimensions derived from the Institute of Medicine, using key performance indicators and benchmarked to give feedback twice a year to individual physicians, hospital administrators and quality review teams on how they compare

against a set threshold of good quality. Currently, 83% of orthopaedic surgeons participate in the programme, representing 95% of the total volume of THA and TKA. In another QI project performed in the UK, a reduction in LOS was achieved from 3.6 to 2.4 days in one hospital for THA and TKA and 3.6 to 2.0 days in another, both by the introduction of PDSA cycles to improve on postoperative analgesia, physiotherapy and local policy.³⁵

A previous study targeting quality of pain management in intensive care units showed an improvement in pain management when an action implementation toolbox was added to feedback compared with feedback alone, but only in process indicators and not in clinical outcomes.²³ The present study therefore adds that a comparable intervention where the toolbox included evidence-based measures targeting outcomes rather than merely process measures such as having a protocol in place, was effective in improving patient outcomes.

Strengths and limitations of this study

The strengths of this study include the robust randomised trial design, limited selection bias given that LROI data include more than 99% of all primary THA and TKA performed, and the required sample size of the power calculation achieved.^{29 30} In addition, the intervention was developed guided by evidence and following the latest theory and recommendations.^{22 23 36} The risk of contamination among control hospitals seems unlikely because control hospitals were not aware of the start of the implementation period and received the intervention at a later point in time, and feedback was tailored to a specific hospital. If contamination did occur, this would have diluted the intervention effect so that the true effect would potentially be larger. In addition, given the lower pre-implementation TO in control hospitals than in intervention hospitals, one would expect a larger change in control hospitals due to more potential for improvement and regression to the mean, making the opposite effect all the more notable.^{19 37}

However, some limitations remain. First, the potential influence of a Hawthorne effect on study findings was largely compensated by control hospitals, as performance improved in both hospital groups. Second, information bias may occur if coding accuracy changed within hospitals between periods and differently for intervention than control hospitals. This seems unlikely, including that it would occur to such an extent that it would explain our results. Third, since outcome frequencies vary considerably between performance indicators, TO is dominated by long LOS, a well-known disadvantage of binary all-or-none composite outcomes.^{38 39} However, estimates for the individual outcomes largely went in the same direction, although non-significant.

Fourth, implementing the intervention in a specific country and for a specific type of surgery limits the generalisability of the results. Thus, the feasibility and impact of the intervention in a different context requires further study. Finally, patients were not involved in the design of this study which could have resulted in different outcomes being targeted by QI initiatives.

Implications and future research

Even though the multifaceted QI intervention in the present study was shown to improve the quality of delivered care, the question is what is needed for hospitals to sustain these effects and potentially continue improving further. Only few studies describe how QI interventions became adopted in everyday practice.^{40–43} Implementing a bundle of common QI interventions (eg, staff education, A&F, alerts) to ‘quick fix’ poor hospital performance may provide a temporary solution, but is not sustainable.^{40 41} It appears from the emerging literature that sustainable interventions must provide solutions for the underlying problem. Only through understanding the problem, both an effective and a sustainable intervention can be created that becomes part of everyday practice in the long term.⁴⁴ This may require that first an effective intervention needs to be found, to then solve how it can be adapted for everyday practice to be sustainable, using resources that remain available after the QI intervention ends.⁴⁵ In the present study’s design, it was taken into account that intervention components would remain available for the LROI to apply them in other hospitals if the intervention proved to be effective. The CUSUM charts developed for the intervention are currently being implemented by the LROI.²⁵ In addition, the educational video and pocket card remain available, as well as the toolbox which can be kept up-to-date and further expanded with new effective QII appearing in the literature. Also, an annual educational session or workshop may keep hospitals both engaged to continue improving their care and act as further education, where participants in the current study may act as champions to share what worked and what not. Further engagement can also be supported by the toolbox being continuously updated as participants share and use each other’s best practices and experiences, rather than a static list that may become outdated when new evidence appears.

CONCLUSIONS

The effect of QI interventions is known to vary, but an optimal design will reasonably improve patient care. The multifaceted intervention in the present study has shown that monthly updated feedback, education, an evidence-based implementation toolbox with suggested QII, and bimonthly surveys

achieve a statistically significant larger improvement in outcomes for patients undergoing THA and TKA. The intervention effect was most likely achieved by introducing targeted QII particularly reducing long LOS.

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Ethics approval This study involves human participants but LUMC Medical Ethical Committee, G18.140, exempted this study. No persons are subjected to treatment or are required to behave in a certain manner.

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Correction: *Effectiveness of a multifaceted quality improvement intervention to improve patient outcomes after total hip and knee arthroplasty: a registry nested cluster randomised controlled trial*

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The IQ Joint study group has been added to the author list. In addition to this, blinded data in the methods section has been updated with the correct information.

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Hospital anonymised

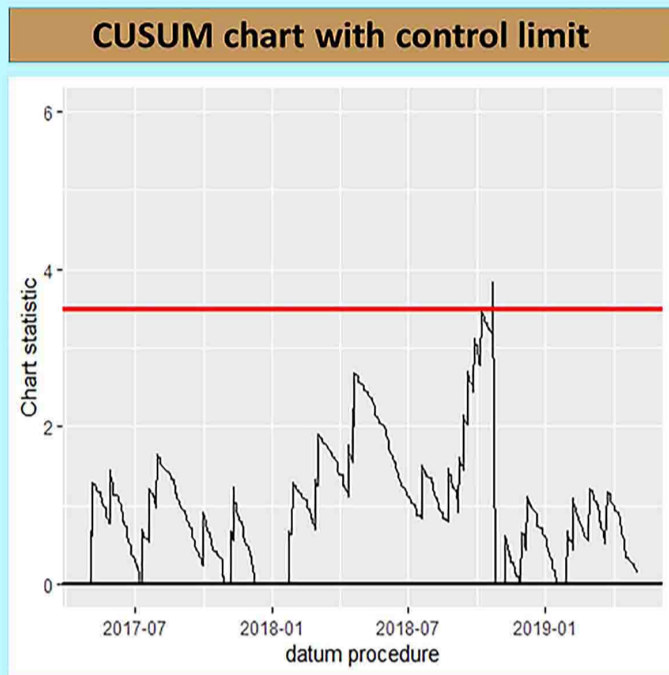
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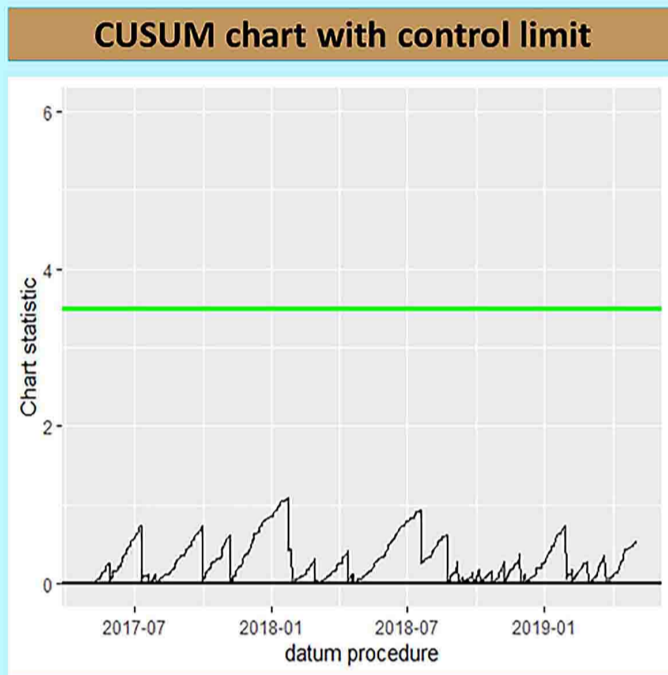
Monthly Feedback

Primary Total Hip Arthroplasty

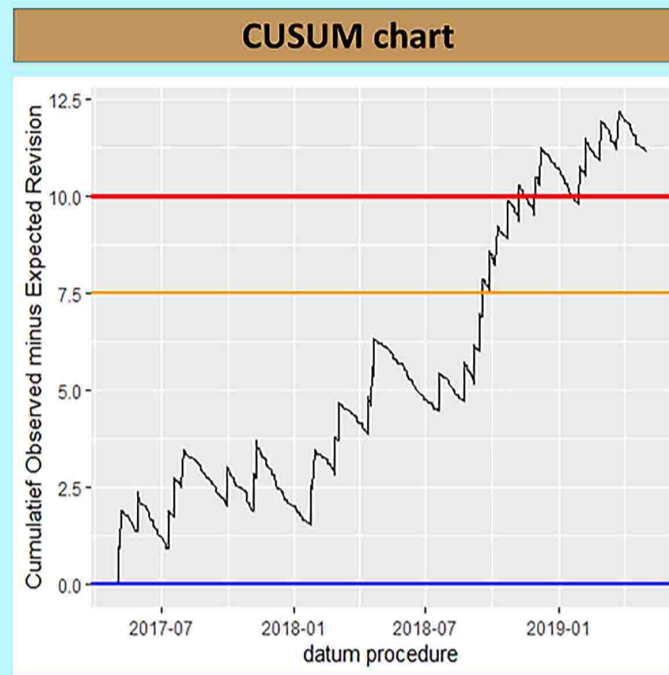
Revision within 1 year adjusted for case-mix. Data from the last 12 months were excluded for follow-up.



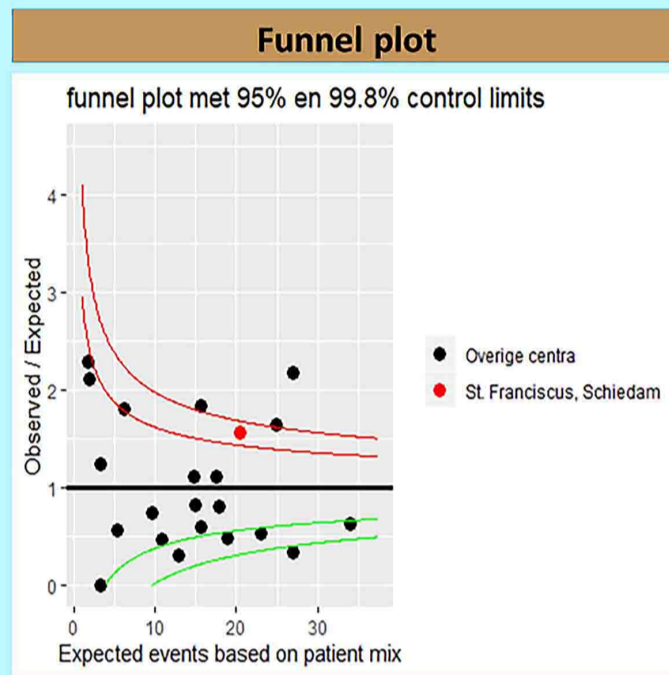
In this graph, the operations are arranged by operation date (x-axis). In an upward trend, your center has more revisions than expected. When the black line crosses the red line, your center performs with 95% confidence twice as many revisions as expected based on patient characteristics, calculated in the total study group. After crossing the red line, the black line is reset to 0.



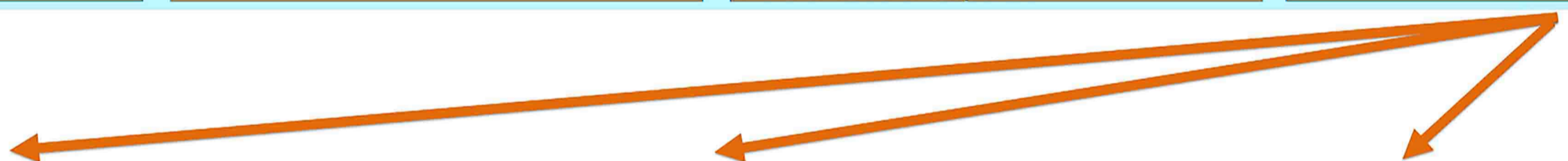
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This graph shows the expected number of revisions per center on the x-axis. The centers with larger numbers of patients are more to the right than the smaller centers. The y axis shows the observed number of revisions divided by the expected number of revisions based on case-mix. Your hospital has significantly more revisions within 1 year than the average of the study group.

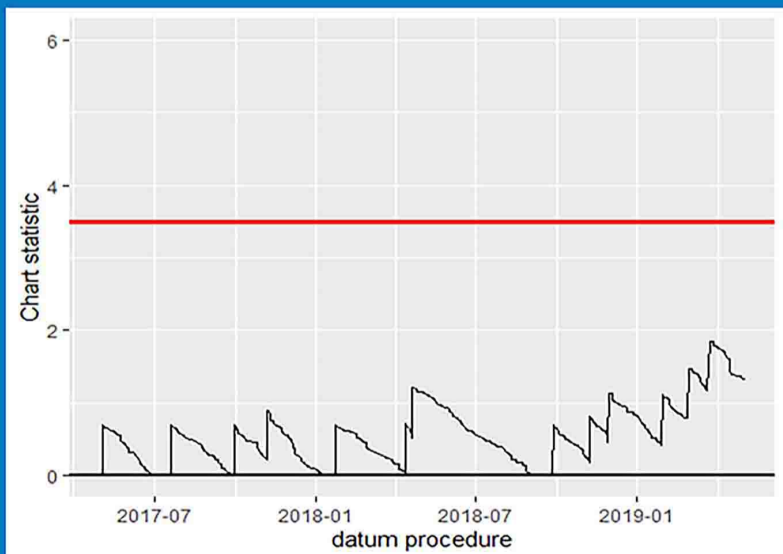
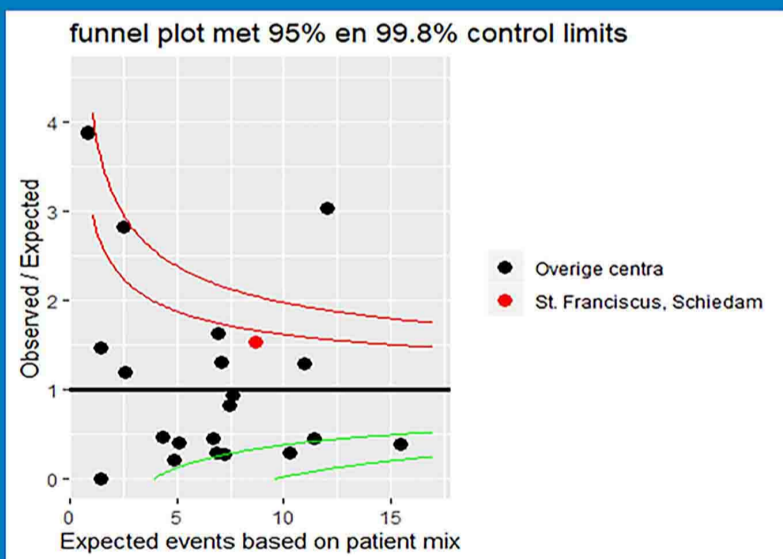


Revision within one year adjusted for case-mix due to infection, dislocation and prosthesis loosening. A higher number for one of these outcomes indicates targeted initiatives for quality improvement.

blinded

Revision within 1 year due to infection

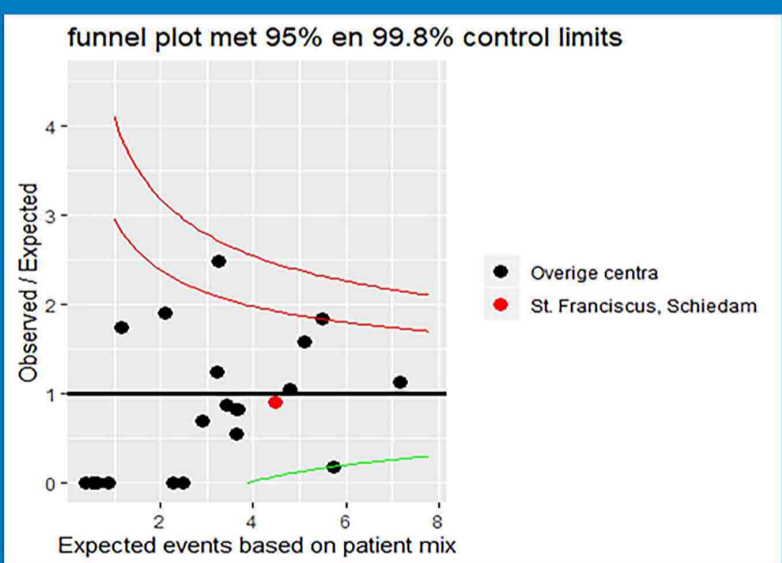
Funnel plot + CUSUM chart



Revision within one year due to dislocation

Description + Funnel plot

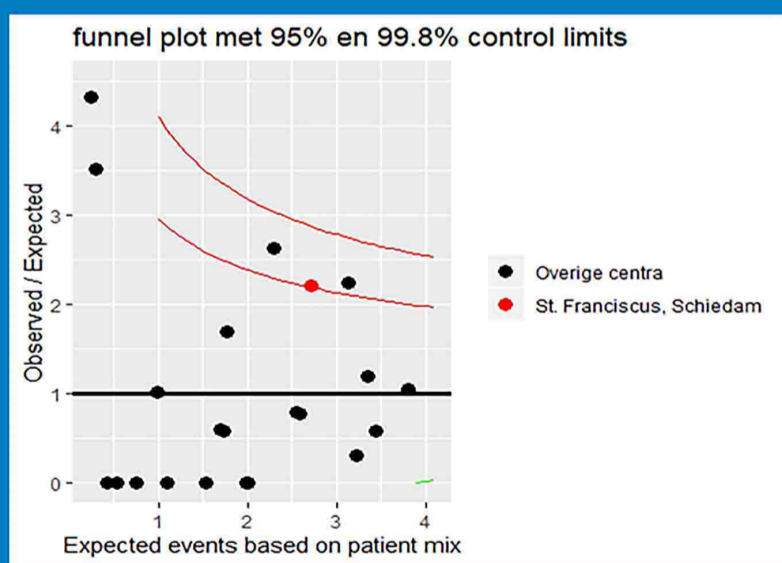
Your hospital has performed 4 revisions within 1 year due to infection



Revision within 1 year due to prosthesis loosening

Description + Funnel plot

Your hospital has performed 6 revisions within 1 year due to prosthesis loosening




blinded



blinded




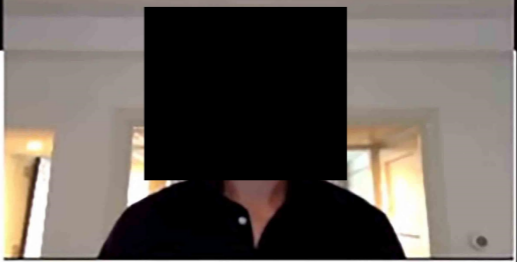
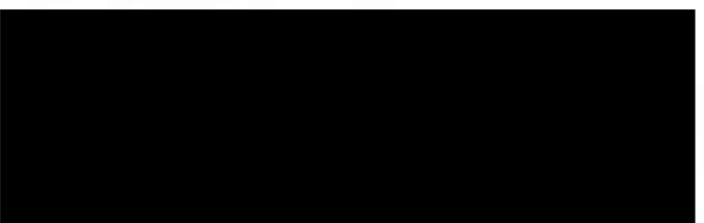
YouTube NL Zoeken



Leiden University
Medical Center


Maandelijks Feedback IQ Joint Project

Interpretatie van de prestatie-uitkomsten



Leiden University Medical Center

1. Orthopedisch chirurgie
2. Medische beslistkunde

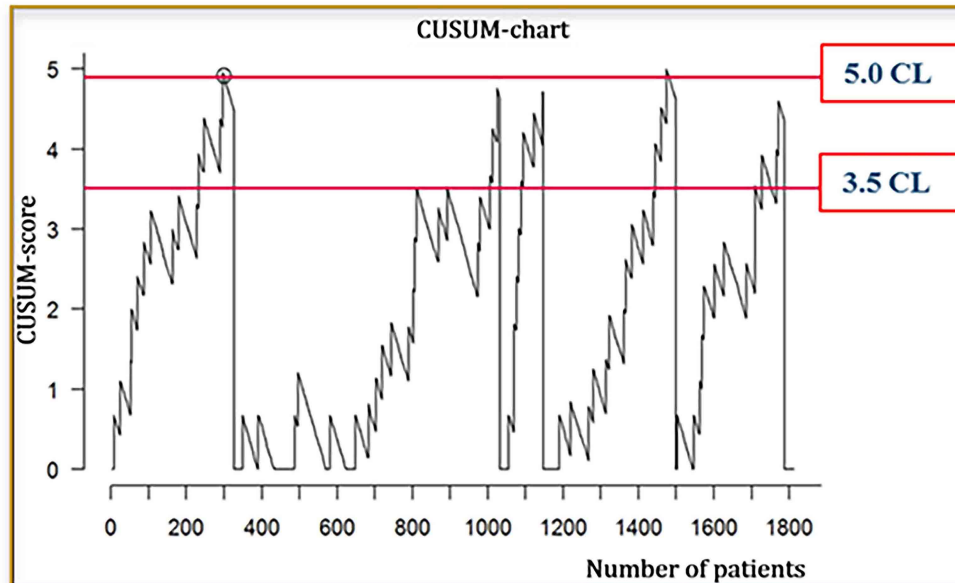


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CUSUM-chart

Things you should know

A Cumulative sum (CUSUM) chart can be used to monitor continuously for every patient whether performance is as expected or becomes worse than expected.



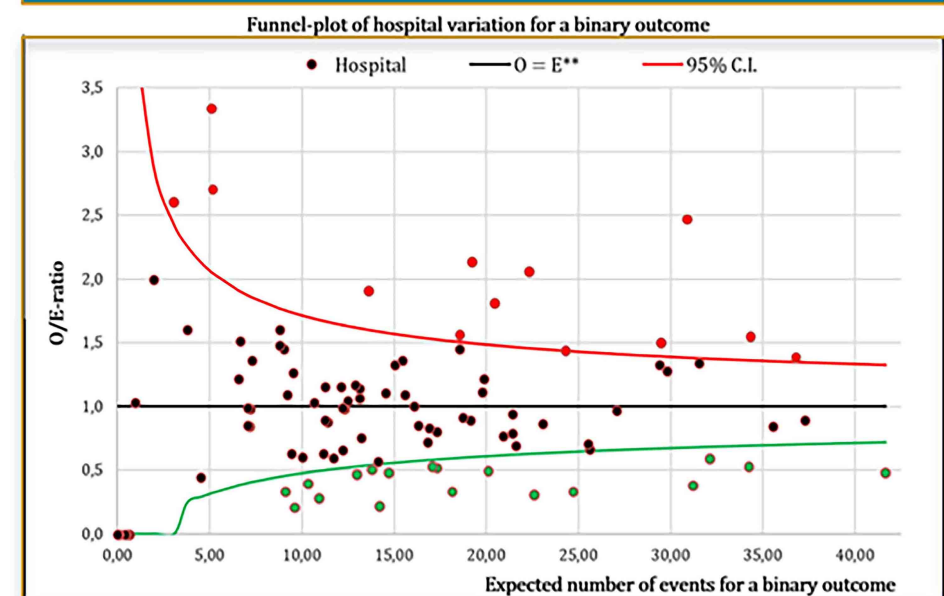
1. For every consecutive patient, the observed (O) minus expected (E) probability for an event is plotted.
2. When the score goes upward this means that the observed performance for that patient is worse than expected, vice versa when going down.
3. A signal (alert) is generated when crossing the control limit (CL). The chart is reset to zero.
4. A higher CL means we are increasingly certain this is a true signal. CL 5.0 thus has fewer false positive signals but could miss cases of worse performance. The opposite applies to 3.5 CL.



Funnel-plot

Things you should know

Funnel-plots are recommended as a graphical aid to show the variation between hospitals in performance, and identify hospitals performing worse (in red) or better (in green) than expected



1. The expected probability on an outcome is calculated for each patient given e.g. age, comorbidity and smoking. These probabilities are summed for all patients treated in a hospital to calculate the expected number.
2. The O/E-ratio is the observed number of events divided by the expected number of events for a hospital.
3. When O/E-ratio=1, the observed number equals the expected number of events in that hospital.
4. Hospitals plotted between the two control limits have a performance that is not statistically different from what is expected based on their patient-mix.
5. Hospitals plotted above the upper control limit have more events than expected based on their patient mix (performing worse) – negative outliers.
6. Hospitals plotted below the lower control limit have fewer events than expected based on their patient mix (performing better) – positive outliers.

Toolbox

Content of Toolbox

In this toolbox we offer starting points for quality improvement initiatives based on the currently available literature. The chapters are ordered according to the performance outcomes as offered in the monthly feedback. It is noted that this is not an exhaustive list.

We advise to implement quality improvement initiatives according to the Plan-Do-Check-Act cycle.

Plan-Do-Check-Act cycle	2
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Performance outcomes

- | | |
|--|----|
| • 1-year revision rate due to infection (THA & TKA) | 3 |
| • 1-year revision rate due to prosthesis loosening (THA&TKA) | 5 |
| • 1-year revision rate due to dislocation (THA) | 7 |
| • 1-year revision rate due to technical failure (TKA) | 9 |
| • Length-of-stay in hospital | 11 |
| • Readmissions | 13 |
| • Textbook Outcome & Ordinal Composite Outcome Measure | 15 |

Surveys

The survey was emailed every two months together with the feedback to evaluate adherence to the intervention, encourage reviewing the feedback, introduce QII if necessary, and stimulate trial engagement. Participants could report best practices and experiences to be added to the toolbox and shared with others, also to stimulate trial engagement. The questionnaire has been translated from Dutch.

1. Have you read and interpreted the monthly feedback containing the performance outcomes of primary total hip and/or knee arthroplasties (THP/TKP)?
 - a. Yes, the feedback was clear
 - b. Yes, but the feedback was not clear because
 - c. No, I did not get around to this

2. Has the feedback been discussed within your department?
 - a. Yes, we saw potential to improve at least one of the performance outcomes
 - b. Yes, but we did not see any potential to improve one of the performance outcomes
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3. Are there any performance outcomes for which, according to the feedback, your center underperforms or has performed worse than the average for the IQ Joint study group? You may select multiple outcomes.
 - a. Revision within one year
 - b. Readmission within 30 days
 - c. Complications within 30 days
 - d. Long length of stay
 - e. None

4. For which performance outcome(s) have improvement initiatives been undertaken since the start of the study (October 2019)? Enter what you/your healthcare institution have done in the free text field below the relevant performance outcome. You may select multiple outcomes.
 - a. Revision within one year
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 - b. Readmission within 30 days
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 - i.
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 - e. None

5. If applicable, indicate for each improvement initiative undertaken to improve a performance outcome, how your center chose this improvement initiative.

	Toolbox	Literature	Expert advice	Other (free text field)	No improvement
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					initiative undertaken for this outcome
Revision	Yes/No	Yes/No	Yes/No	Yes/No
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Complications	Yes/No	Yes/No	Yes/No	Yes/No
Long length of stay	Yes/No	Yes/No	Yes/No	Yes/No

6. What would you or your center need to improve further? You may select multiple answers.
- Further explanation of the interpretation of performance outcomes in the feedback
 - Link to another center that scores better for an outcome for which we score worse
 - More items in the toolbox, namely
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Hospital anonymised

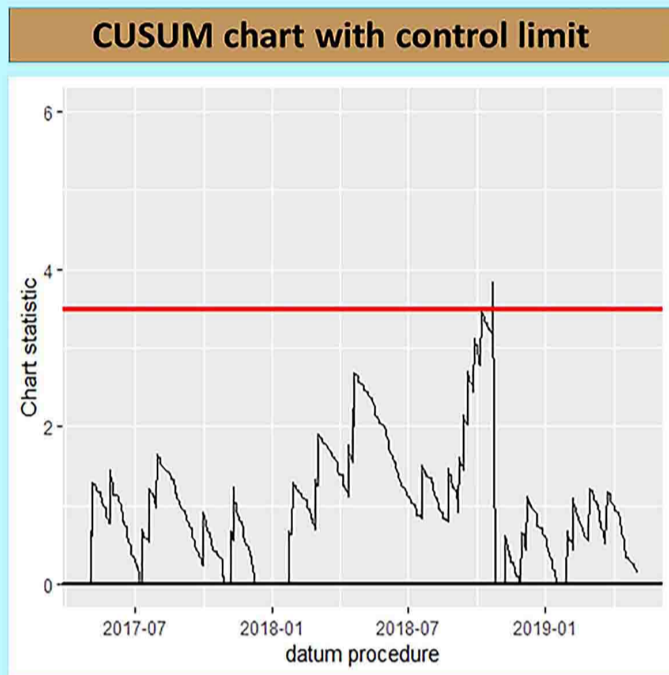
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Blinded

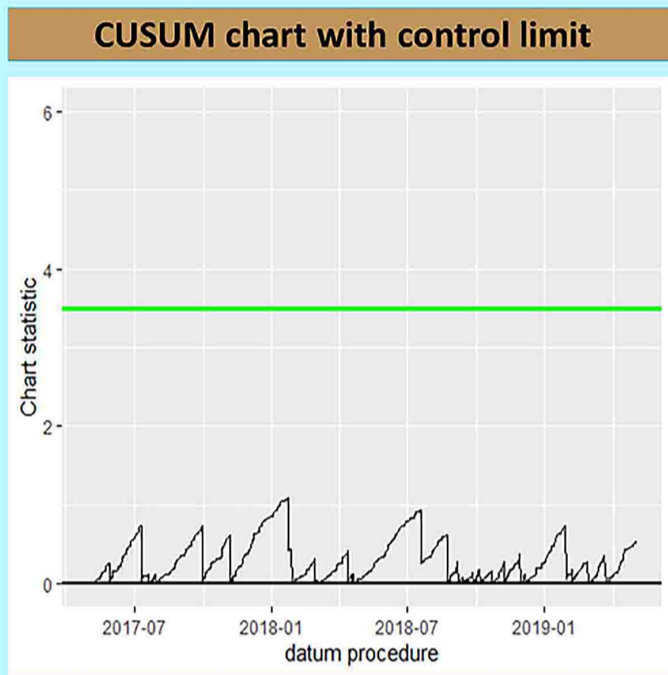
Monthly Feedback

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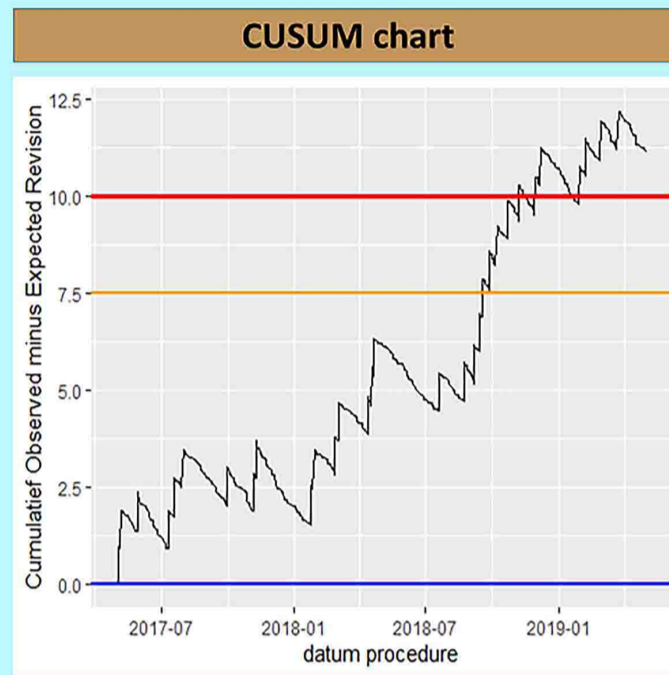
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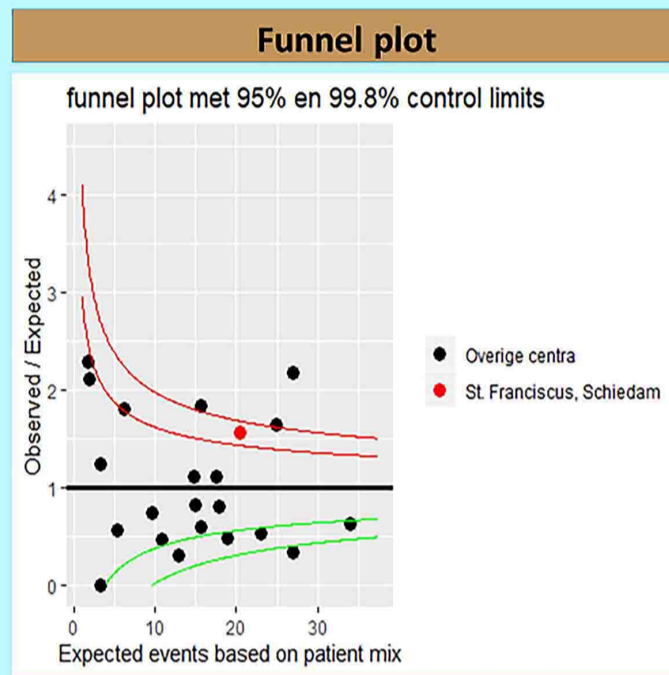
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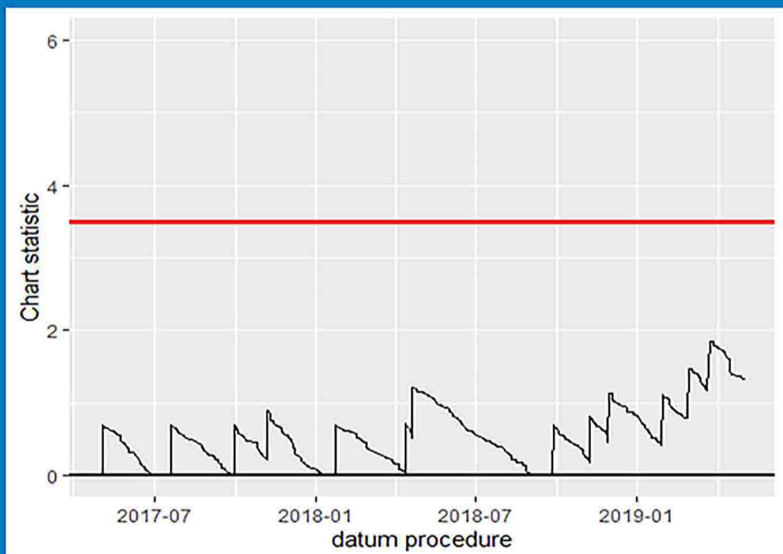
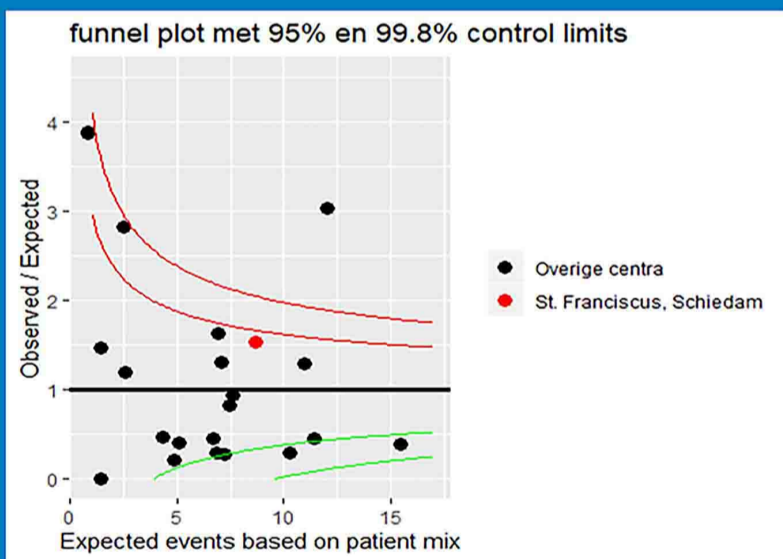


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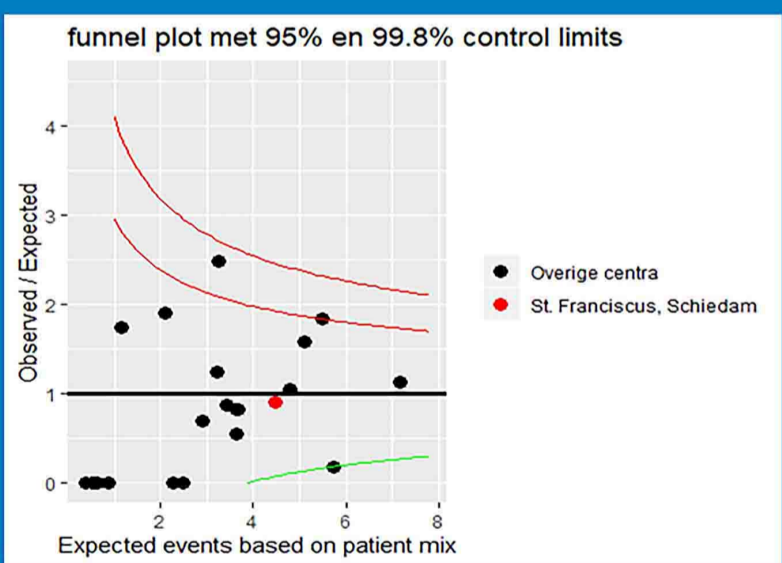
Funnel plot + CUSUM chart



Revision within one year due to dislocation

Description + Funnel plot

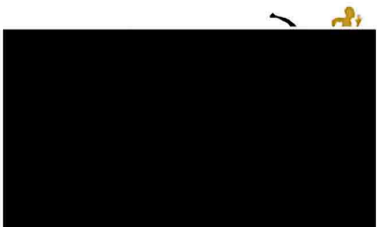
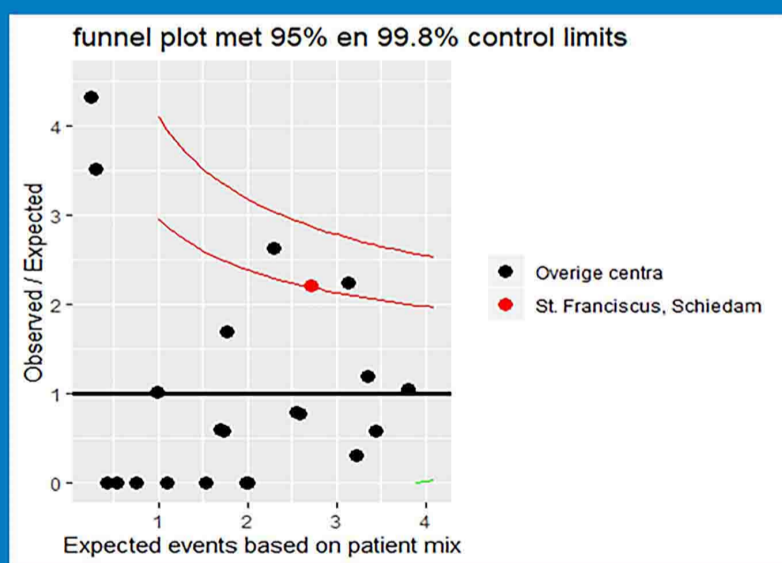
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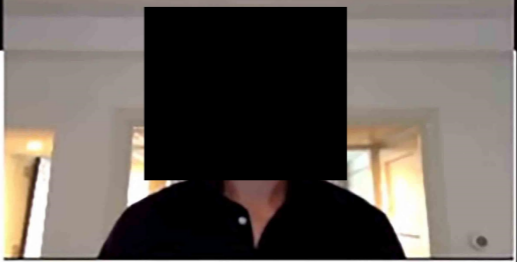
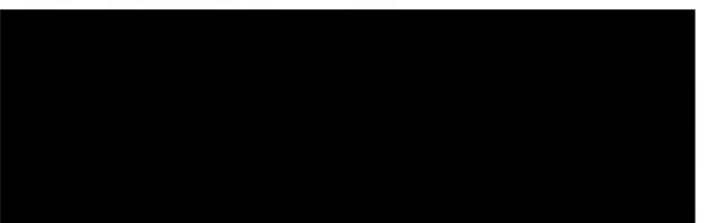
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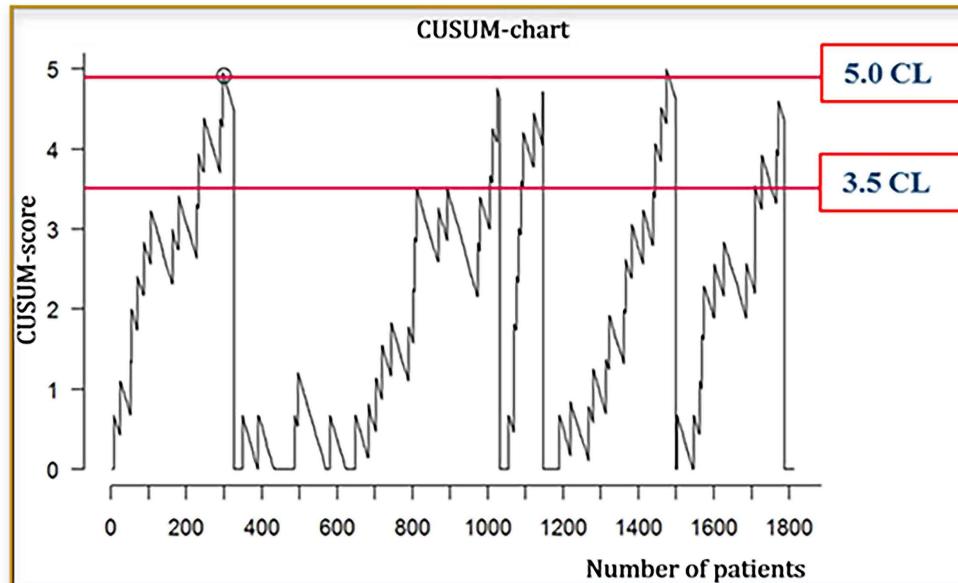


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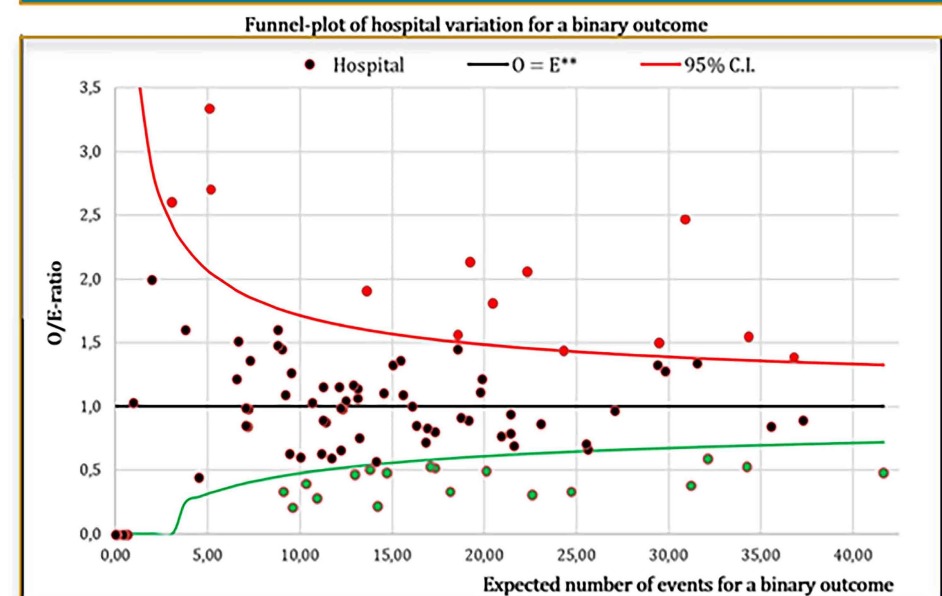
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