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# Monitoring Hospital Performance with Statistical Process Control After Total Hip and Knee Arthroplasty

A Study to Determine How Much Earlier Worsening Performance Can Be Detected

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**Background:** Given the low early revision rate after total hip arthroplasty (THA) and total knee arthroplasty (TKA), hospital performance is typically compared using 3 years of data. The purpose of this study was to assess how much earlier worsening hospital performance in 1-year revision rates after THA and TKA can be detected.

**Methods:** All 86,468 THA and 73,077 TKA procedures performed from 2014 to 2016 and recorded in the Dutch Arthroplasty Register were included. Negative outlier hospitals were identified by significantly higher O/E (observed divided by expected) 1-year revision rates in a funnel plot. Monthly Shewhart p-charts (with 2 and 3-sigma control limits) and cumulative sum (CUSUM) charts (with 3.5 and 5 control limits) were constructed to detect a doubling of revisions (odds ratio of 2), generating a signal when the control limit was reached. The median number of months until generation of a first signal for negative outliers and the number of false signals for non-negative outliers were calculated. Sensitivity, specificity, and accuracy were calculated for all charts and control limit settings using outlier status in the funnel plot as the gold standard.

**Results:** The funnel plot showed that 13 of 97 hospitals had significantly higher O/E 1-year revision rates and were negative outliers for THA and 7 of 98 hospitals had significantly higher O/E 1-year revision rates and were negative outliers for TKA. The Shewhart p-chart with the 3-sigma control limit generated 68 signals (34 false-positive) for THA and 85 signals (63 false-positive) for TKA. The sensitivity for THA and TKA was 92% and 100%, respectively; the specificity was 69% and 51%, respectively; and the accuracy was 72% and 54%, respectively. The CUSUM chart with a 5 control limit generated 18 signals (1 false-positive) for THA and 7 (1 false-positive) for TKA. The sensitivity was 85% and 71% for THA and TKA, respectively; the specificity was 99% for both; and the accuracy was 97% for both. The Shewhart p-chart with a 3-sigma control limit generated the first signal for negative outliers after a median of 10 months (interquartile range [IQR] = 2 to 18) for THA and 13 months (IQR = 5 to 18) for TKA. The CUSUM chart with a 5 control limit generated the first signal after a median of 18 months (IQR = 7 to 22) for THA and 21 months (IQR = 9 to 25) for TKA.

**Conclusions:** Monthly monitoring using CUSUM charts with a 5 control limit enables earlier detection of worsening 1-year revision rates with accuracy so that initiatives to improve care can start earlier.

Most arthroplasty registries publish annual reports including funnel plots for binary clinical outcomes, with the purpose of monitoring hospital performance and providing feedback. Funnel plots are graphical tools to compare outcomes with those of other hospitals and detect hospitals performing significantly better or worse in terms of

these outcomes. In orthopaedics, the 1-year revision rate is an important performance indicator to monitor quality of hospital care. Consequences of a revision are dramatic for patients and entail considerable costs. However, due to low event rates for 1-year revision as well as for many orthopaedic performance outcomes, multiple years of outcomes are usually

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combined in funnel plots to obtain detectable and reliable hospital differences<sup>1-6</sup>. Because arthroplasty registries typically combine 3 years of data, it may take a long time before deteriorating performance is noticed, resulting in late action plans to improve care<sup>3</sup>. Thus, more frequent monitoring of clinical end points such as 1-year revision rates is needed, as are reliable and earlier signals if outcomes deteriorate.

Statistical process control (SPC) charts such as Shewhart p-charts and cumulative sum (CUSUM) charts may offer additional information because the performance is plotted more frequently over time (for example, monthly). Several good clinical studies and the focus to improve the quality of care led to growing interest in these charts<sup>7-16</sup>. SPC charts with their control limits can distinguish between an “in-control” process, showing only chance variation within control limits, and an “out-of-control” process, showing systematic (special-cause) variation and generating a signal (alert) when the control limit is reached<sup>17</sup>. However, with SPC charts there is a trade-off between the number of false-positive and the number of false-negative signals, determined by the level at which control limits are set. In practice, minimization of the number of false-positive signals in particular is recommended because they may result in alert and improvement fatigue by clinicians<sup>18,19</sup>.

Various SPC charts are available, but there is uncertainty about which chart and control limit to choose<sup>20,21</sup>. In the present study, we opted for Shewhart p-charts and CUSUM charts. The Shewhart p-chart is considered to be accessible, especially with regard to implementation and easy interpretation<sup>22</sup>. However, the CUSUM chart has superior performance in detecting small (<10%) and large (>10%) increases in event rates<sup>13,22-24</sup>. These 2 SPC charts thus seemed logical candidates to test. The authors of a previous orthopaedic study already described CUSUM-chart implementation but did not address how much earlier a signal was generated or its reliability compared with the more commonly used funnel plot, which seem crucial for these techniques to be accepted in routine clinical practice<sup>25</sup>.

The aim of this study was to assess the extent to which Shewhart p-charts and CUSUM charts enable monitoring such that worsening 1-year revision total hip arthroplasty (THA) or total knee arthroplasty (TKA) rates in Dutch hospitals are detected earlier within a time frame of 3 years, with good sensitivity, specificity, and accuracy, compared with the current method of arthroplasty registries using funnel plots.

## Materials and Methods

### Study Design

This observational study used routinely collected data from the nationwide Dutch Arthroplasty Register (Landelijke Registratie Orthopedische Implantaten [LROI])<sup>6</sup>. Data completeness in this register is checked against in-hospital patient records and currently exceeds 98% for primary arthroplasties and 96% for revisions<sup>26,27</sup>.

### Study Population

All Dutch patients who underwent a primary THA or TKA procedure from January 2014 to December 2016 as recorded in

the LROI were included. The following patient characteristics were available: age, sex, body mass index (BMI, in kg/m<sup>2</sup>), smoking (yes or no), American Society of Anesthesiologists (ASA) classification, Charnley score (A, B1, B2, C, and not applicable), and diagnosis (osteoarthritis or non-osteoarthritis)<sup>28</sup>. Revision within 1 year (yes or no) was the primary outcome measure (defined as replacement, removal, or addition of any component).

### Statistical Analysis

The between-hospital variation in 1-year revision rates after primary THA and TKA during 2014 to 2016 was estimated, applying the same method as used by the LROI. For each patient, the expected revision risk was calculated using logistic regression analysis, including all patient characteristics described above as independent variables and 1-year revision as the dependent variable. Missing patient characteristic values (<10% for all variables) were imputed with the mean for numeric variables or the mode for categorical variables (meaning that the most frequently occurring category was imputed). All expected revision risks were then summed within a hospital to obtain the aggregated expected number (E) of revisions per hospital. The observed numbers (O) divided by expected numbers were depicted in a funnel plot with 95% control limits. Negative outlier hospitals are those outside the upper limit, meaning that they had significantly higher revision rates than expected given their patient mix. Positive outlier hospitals are those outside the lower limit, meaning that they had significantly lower revision rates.

Second, the extent to which SPC methods can generate an earlier signal for deteriorating performance within a 3-year time frame was estimated. Risk-adjusted monthly Shewhart p-charts (with 2 and 3-sigma control limits) and risk-adjusted log-likelihood CUSUM charts (with 3.5 and 5 control limits) for 1-year revisions were constructed to detect an odds ratio of 2 for each hospital across 3 years<sup>22</sup>. Figure 1 shows an example of a Shewhart p-chart, in which the center line indicates the mean hospital performance and the area between both control limits is where variation is considered random (by chance). A value outside the control limits is considered a systematic variation and generates a signal. Usually 2 and 3-sigma control limits are used, with the 2-sigma control limit having a higher likelihood of a type-1 error (false-positive signal) and the 3-sigma control limit having a higher likelihood of a type-2 error (false-negative signal). Figure 2 shows an example of a CUSUM chart with 3.5 and 5 control limits. This chart shows the cumulative performance across patients over a period of time. When the chart statistic reaches the control limit, a signal is generated and the chart resets to zero. Similarly, the control limits are chosen to balance the likelihood of false-positive and false-negative signals, with 3.5 and 5 most commonly used in practice<sup>22,25</sup>. Appendix I gives a more detailed description of the Shewhart p-chart and CUSUM chart.

For both charts and control-limit settings, we calculated the median number of months needed to generate the first

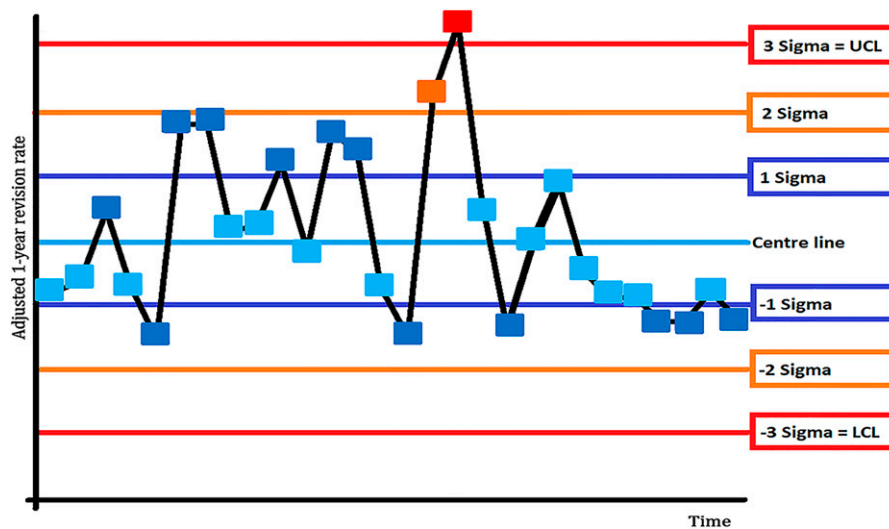


Fig. 1  
Example of a Shewhart p-chart. UCL = upper control limit and LCL = lower control limit. See text for explanation of chart.

signal for negative outlier hospitals and the number of false signals for other hospitals. Furthermore, we calculated the signals missed for negative outlier hospitals. Additionally, sensitivity, specificity, and accuracy for both charts and control-limit settings were calculated within the 3-year time frame using the negative outlier status of a hospital in the funnel plots as the standard. The accuracy for correctly classifying a hospital was defined as:  $([\text{number of true-positive hospitals} + \text{number of true-negative hospitals}]/\text{total number of hospitals}) \times 100\%$ .

Analyses were performed using SPSS, version 25 (IBM). The LUMC Medical Ethical Committee considered the study exempt for ethical approval under Dutch law (CME, G18.140).

### Results

The study included 86,468 primary THA procedures from 97 hospitals and 73,077 primary TKA procedures from 98 hospitals. The rate of missing data was <4% for all variables except for smoking (<10%). On the patient level, the average 1-year revision rate was 1.8% for THA and 1.2% for TKA. On the

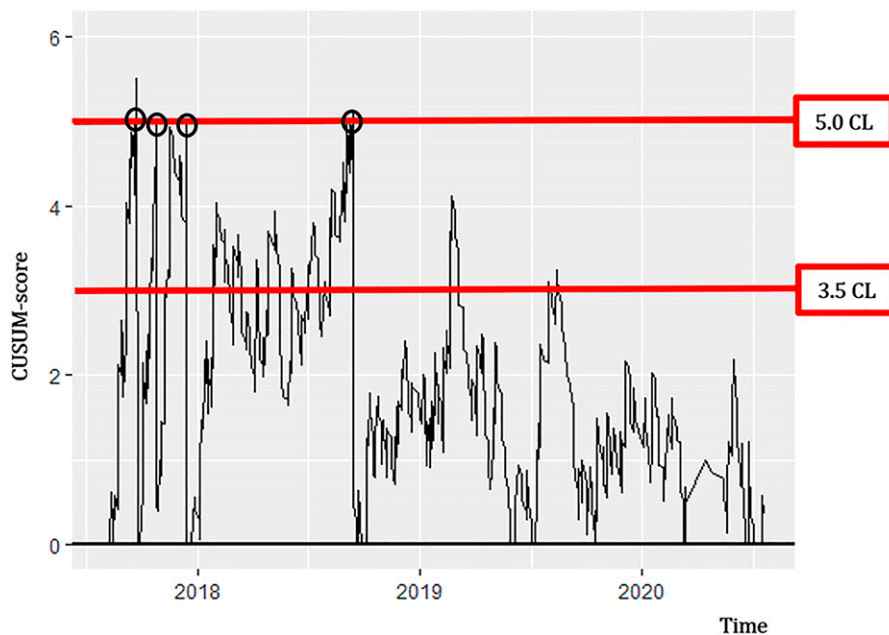


Fig. 2  
A hypothetical CUSUM chart with 3.5 and 5 control limits (CL). The chart resets to 0 after the 5 control limit is reached. In this example, 4 signals are generated and the hospital shows an improvement for this outcome over time. See text for further explanation of chart.

**TABLE I** Distribution of Patient Characteristics and Outcomes in Participating Hospitals\*

	THA (N = 97 Hospitals)		TKA (N = 98 Hospitals)	
	Median (IQR)	Range	Median (IQR)	Range
Procedures (no.)	759 (526-1,173)	2-2,502	699 (463-938)	9-1,998
Mean age (yr)	69.3 (67.8-70.1)	50.6-71.8	68.8 (67.4-69.7)	56.5-72.2
Female sex (%)	66.1 (63.3-68.0)	0.0-74.1	65.2 (61.9-67.8)	8.3-100.0
Mean BMI (kg/m <sup>2</sup> )	27.3 (27.0-27.8)	25.9-28.6	29.8 (29.3-30.4)	20.5-31.0
Smoking (%)	13.2 (10.7-15.2)	0.0-27.9	9.8 (8.4-11.8)	1.0-20.5
ASA classification (%)				
I	17.4 (14.2-21.4)	3.3-100	11.8 (9.8-16.0)	3.8-54.5
II	65.0 (59.8-70.4)	0.0-96.7	68.7 (63.7-73.6)	42.5-91.6
III or IV	15.6 (11.5-20.4)	0.0-40.1	16.6 (10.8-21.8)	0.0-50.6
Charnley score† (%)				
A	49.3 (43.7-53.9)	23.7-78.2	45.3 (35.6-52.4)	13.1-100.0
B1	27.8 (22.9-33.4)	3.6-50.7	33.0 (27.3-40.3)	0.0- 57.8
B2	20.1 (18.1-22.9)	4.7-28.3	19.4 (16.2-21.5)	0.0-28.0
C	1.9 (1.0-3.3)	0.0-12.2	2.3 (1.1-4.2)	0.0-17.4
Diagnosis (%)				
Osteoarthritis	87.1 (83.5-90.8)	42.2-100.0	96.6 (95.5-97.9)	58.6-100.0
Non-osteoarthritis‡	12.9 (9.3-16.5)	0.0-57.8	3.4 (2.1-4.5)	0.0-41.4
1-year revisions (%)	1.6 (1.0-2.3)	0.0-7.0	1.1 (0.7-1.6)	0.0-16.7

\*The values under “Median (IQR)” indicate the mean or the percentage of the median hospital. The values under “Range” indicate the highest and lowest means or percentages among the hospitals. †The Charnley score was used to evaluate comorbidity in relation to levels of activity. ‡All diagnoses except osteoarthritis (fracture, osteonecrosis, rheumatoid arthritis, inflammatory arthritis, etc.).

hospital level, the median revision rate was 1.6% (interquartile range [IQR] = 1.0% to 2.3%) for THA and 1.1% (IQR = 0.7% to 1.6%) for TKA (Table I).

### Outlier Hospitals

Based on 3-year funnel plots, 13 hospitals performing THA were negative outliers with a median O/E (observed divided by expected) ratio of 1.9 (IQR = 1.5 to 2.5) compared with 0.9 (IQR = 0.5 to 1.1) for the other hospitals. For TKA, there were 7 negative outliers with a median O/E ratio of 2.3 (IQR = 2.3 to 2.8) compared with 0.8 (IQR = 0.6 to 1.2) for the other hospitals (Table II and Appendices II and III; red dots). Two hospitals were negative outliers for both THA and TKA. Eighteen hospitals were positive outliers for THA, with a median O/E ratio of 0.4 (IQR = 0.3 to 0.5), and 14 hospitals were positive outliers for TKA, with a median O/E ratio of 0.3 (IQR = 0.2 to 0.5) (Appendices II and III; green dots).

### Earlier Signals Compared with False Signals Using 2 SPC Methods

#### Shewhart P-Chart

For THA, 195 signals of worsening performance were generated for 70 hospitals at the 2-sigma (similar to 2 standard deviations in hypothesis testing) control limit, with all 13 negative outlier hospitals alerted but also 57 hospitals incorrectly alerted (sen-

sitivity = 100%, specificity = 32%, accuracy = 41%). At the 3-sigma control limit, 68 signals were generated for 38 hospitals, with 12 negative outlier hospitals alerted (sensitivity = 92%, specificity = 69%, accuracy = 72%). At 3 sigma, the first signal for negative outliers was generated after a median of 10 months (IQR = 2 to 18), which should be considered against 34 false-positive signals for other hospitals. For 1 negative outlier hospital, no signal was generated. More than 1 signal was generated for 9 negative outliers and 7 other hospitals (Table III).

For TKA, 214 signals were generated for 85 hospitals at the 2-sigma control limit, with all 7 negative outlier hospitals alerted (sensitivity = 100%, specificity = 14%, accuracy = 20%), and 85 signals were generated for 52 hospitals at 3 sigma (sensitivity = 100%, specificity = 51%, accuracy = 54%). At 3 sigma, the first signal for negative outliers was generated after a median of 13 months (IQR = 5 to 18), which should be considered against 63 false-positive signals. All negative outlier hospitals were alerted. More than 1 signal was generated for 6 negative outliers and 14 other hospitals (Table III).

#### CUSUM Chart

For THA, 33 signals were generated for 16 hospitals at the 3.5 control limit (sensitivity = 85%, specificity = 94%, accuracy = 93%), and 18 signals were generated for 12 hospitals at the 5 control limit, correctly alerting 11 of 13 negative outliers

**TABLE II O/E Ratios for Negative Outlier Hospitals (Significantly More Revisions Than Expected) from 2014 to 2016**

Negative Outlier Hospital	O/E Ratio*	
	THA (N = 13 Hospitals)	TKA (N = 7 Hospitals)
4	1.4	
6	1.5	
9	2.5	2.2
13	1.5	
14	1.4	
21	2.1	
28	1.8	
33	2.1	
37	1.6	
35		2.3
39		2.0
41		2.3
52	1.9	
87	2.7	2.8
88	3.3	
89		2.7
90	2.6	
95		13.3
Median (IQR) for negative outliers	1.9 (1.5-2.5)	2.3 (2.3-2.8)
Median (IQR) for all other Dutch hospitals	0.9 (0.5-1.1)	0.8 (0.6-1.2)

\*An O/E-ratio is provided only for negative outliers during the 3-year period.

(sensitivity = 85%, specificity = 99%, accuracy = 97%). At the 5 control limit, the first signal for negative outliers was generated after a median of 18 months (IQR = 7 to 22), which should be considered against 1 false-positive signal for other hospitals. Two negative outlier hospitals were not alerted. More than 1 signal was generated for 4 negative outliers and none of the other hospitals (Table III).

For TKA, 16 signals were generated for 12 hospitals at the 3.5 control limit (sensitivity = 71%, specificity = 92%, accuracy = 91%), and 7 signals were generated for 6 hospitals at the 5 control limit, with 5 of the 7 outliers correctly alerted (sensitivity = 71%, specificity = 99%, accuracy = 97%). At the 5 control limit, the first signal for negative outliers was generated after a median of 21 months (IQR = 9 to 25), which should be considered against 1 false-positive signal. Two negative outliers were not alerted. More than 1 signal was generated for 1 negative outlier and none of the other hospitals (Table III).

## Discussion

Most arthroplasty registers report revision rates after THA and TKA, as well as differences between hospitals using

funnel plots to detect hospitals with significantly worse performance than others (negative outlier hospitals)<sup>1-6</sup>. Because of the low event rate, this is typically done by combining multiple years of data. The present study shows that monthly monitoring of THA and TKA revision rates using CUSUM charts with the 5 control limit detected worsening performances earlier than did the funnel plots, with good accuracy within a 3-year time frame; the first signal for negative outliers was generated at a median of 18 months for THA and 21 months for TKA. Using CUSUM charts to monitor deteriorating patterns for revision rates thus makes it possible to initiate improvement initiatives earlier rather than waiting for the results to appear in the funnel plot after 3 years.

Some limitations of this study should be noted. First, given the LROI privacy protocol, we could not confirm that the negative outlier hospitals were actually being audited for worse performance by the Dutch Orthopaedic Association. However, since we and the Dutch Orthopaedic Association used both the same data source and the same statistical code to generate the outlier status in a funnel plot, it seems highly unlikely that our identification of negative outliers would have differed. Second, the number of months that the signal generation by the CUSUM chart was earlier than the signal generation by the funnel plot may not be directly generalizable to other countries, but it is likely that the differences in favor of the CUSUM chart are generalizable, particularly because the benefits have been shown previously<sup>25,29</sup>. Third, there is a possibility of insufficient adjustment for differences in patient mix between hospitals because we could control only for those patient characteristics that were collected. However, this limitation would be expected to be similar for both the funnel plot and the SPC charts so it seems unlikely that it affected our conclusions regarding which method is best for detecting changing performance. Fourth, registry data are self-reported by orthopaedic surgeons who may not register all revisions, but given the completeness of the Dutch register we do not believe that this affected our results considerably<sup>26,27</sup>. Fifth, surgeons may postpone revisions, resulting in hospitals having low 1-year revision rates but higher revision rates beyond 1 year. Therefore, using registries to monitor performance reflects daily practice as well as physicians' behavior. We recommend monitoring long-term revision rates (such as at 2 to 5 years) as a balancing measure to check for such occurrences.

There are few examples in orthopaedics of using SPC methods for quality improvement<sup>25,29</sup>. The Scottish Arthroplasty Project reported using the CUSUM chart with the 5 control limit to identify hospital variation in complications<sup>25</sup>. When a signal was generated by exceeding the control limit, surgeons had to submit a review of their complications for assessment by the Scottish Orthopaedic Association. A reduction in complication rates was observed over the last years since the introduction of this quality improvement strategy. However, due to lack of a control group, a causal relationship between CUSUM chart implementation and reduction in complications could not be demonstrated, as a general time trend due to other factors could have been responsible for this reduction. To our knowledge, no empirical studies have been performed to investigate how much earlier worsening

TABLE III Characteristics of SPC Charts

	THA (97 Hospitals; 13 Outliers)				TKA (98 Hospitals; 7 Outliers)			
	Shewhart P-Chart		CUSUM Chart		Shewhart P-Chart		CUSUM Chart	
	2 Sigma	3 Sigma	3.5 Control Limit	5 Control Limit	2 Sigma	3 Sigma	3.5 Control Limit	5 Control Limit
Total no. of signals	195	68	33	18	214	85	16	7
No. (%) generated for negative outliers	76 (39%)	34 (50%)	27 (82%)	17 (94%)	36 (17%)	22 (26%)	9 (56%)	6 (86%)
No. (%) of false signals*	119 (61%)	34 (50%)	6 (18%)	1 (6%)	178 (83%)	63 (74%)	7 (44%)	1 (14%)
Total no. of hospitals with signal	70	38	16	12	85	52	12	6
No. (%) of negative outliers that received a signal	13 (19%)	12 (32%)	11 (69%)	11 (92%)	7 (8%)	7 (13%)	5 (42%)	5 (83%)
No. of false signals† (%)	57 (81%)	26 (68%)	5 (31%)	1 (8%)	78 (92%)	45 (87%)	7 (58%)	1 (17%)
Total no. of hospitals with >1 signal	43	16	9	4	54	20	2	1
No. (%) of negative outliers with >1 signal	13 (30%)	9 (56%)	8 (89%)	4 (100%)	7 (13%)	6 (30%)	2 (100%)	1 (100%)
No. (%) of other hospitals with >1 signal	30 (70%)	7 (44%)	1 (11%)	0 (0%)	47 (87%)	14 (70%)	0 (0%)	0 (0%)
Median time (IQR) to first signal for outliers (mo)	5 (2-10)	10 (2-18)	16 (4-18)	18 (7-22)	5 (3-13)	13 (5-18)	15 (7-22)	21 (9-25)
Sensitivity	100%	92%	85%	85%	100%	100%	71%	71%
Specificity	32%	69%	94%	99%	14%	51%	92%	99%
Accuracy‡	41%	72%	93%	97%	20%	54%	91%	97%

\*Number of signals generated for other hospitals. †Number of other hospitals that received a signal. ‡Accuracy for correctly classifying a hospital: (number of true-positive classified hospitals + number of true-negative classified hospitals)/total number of hospitals) × 100%.

performance could be detected using SPC methods before that worsening appeared as an outlier in funnel plots. These empirical data from daily practice are what the present study adds to the simulations in previous studies that already pointed to more rapid detection of small changes in performance with CUSUM charts. This is relevant for (for example) registries and scientific associations deciding whether to implement such SPC charts in their hospital feedback to initiate quality improvement<sup>22</sup>. By examining patient outcomes over time, SPC charts were able to detect deviating performance even when performance had been “in control” in the past, which may be difficult for a funnel plot to detect because it uses the average outcome over a 3-year period. In addition, the CUSUM chart can be employed to examine the effect of quality improvement initiatives. Using SPC charts thus seems to add relevant information to act upon in daily practice and improve quality of care.

Similar to our study, another study showed the possibility of earlier detection of surgical site infection (SSI) outbreaks using

SPC charts<sup>30</sup>. The Shewhart p-charts and exponentially weighted moving average (EWMA) charts (another SPC chart) in that study both detected 8 of 10 SSI outbreaks (including all 4 orthopaedic-related outbreaks). In each case, a signal was generated prior to signal generation by the traditional detection methods, with a specificity of 70% and 90% for the Shewhart p and EWMA charts, respectively.


The English hospital mortality surveillance system generates CUSUM charts on monthly-collected hospital administrative data<sup>7,8</sup>. After implementation of CUSUM charts, the average risk of death fell by 61% in the 9 months following a signal and reached the level of expected risk within 18 months<sup>7</sup>. It could be that signals were triggered by random variation and subsequent reductions occurred due to regression to the mean (a phenomenon in which extreme outcomes are likely to be followed by a fall in subsequent outcomes)<sup>31</sup>. This may overestimate the effect of a signal. However, findings could also be explained by hospitals

monitoring their own performance and taking action before a signal is generated<sup>7</sup>.

In contrast, one study showed no improvement in incidence rates of ward-acquired methicillin-resistant *Staphylococcus aureus* (MRSA) after implementation of monthly SPC feedback (with or without diagnostic tools)<sup>14</sup>.

In 2017, the Dutch Orthopaedic Association, in collaboration with the LROI, started to identify negative outlier hospitals using funnel plots including 3 years of data, with the aim of providing insight into their clinical practice compared with other Dutch hospitals<sup>32</sup>. This study showed that SPC charts should be included as additional hospital feedback information to provide earlier alerts if performance deteriorates and to provide hospitals with the opportunity to introduce quality improvement initiatives earlier to improve patient care. Further research must be performed to determine whether using SPC charts in daily practice will in fact initiate more quality improvement initiatives, which is the focus of an ongoing randomized controlled trial<sup>33</sup>. Crucial for the effectiveness is that professionals can trust the signals from the SPC chart to be reliable, as was demonstrated by data in this study, and therefore know that they warrant subsequent actions to be taken. Using SPC charts allows initiatives to be introduced earlier than is possible if hospitals wait to become an outlier in a funnel plot.

## Appendix

 Supporting material provided by the authors is posted with the online version of this article as a data supplement at [jbj.org \(http://links.lww.com/JBJS/G132\)](http://links.lww.com/JBJS/G132). ■

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