Supplementary appendix

The economic benefits of surgical outcome monitoring using control charts: the SHEWHART cluster randomized trial

This appendix has been provided by the authors to give readers additional information about their work

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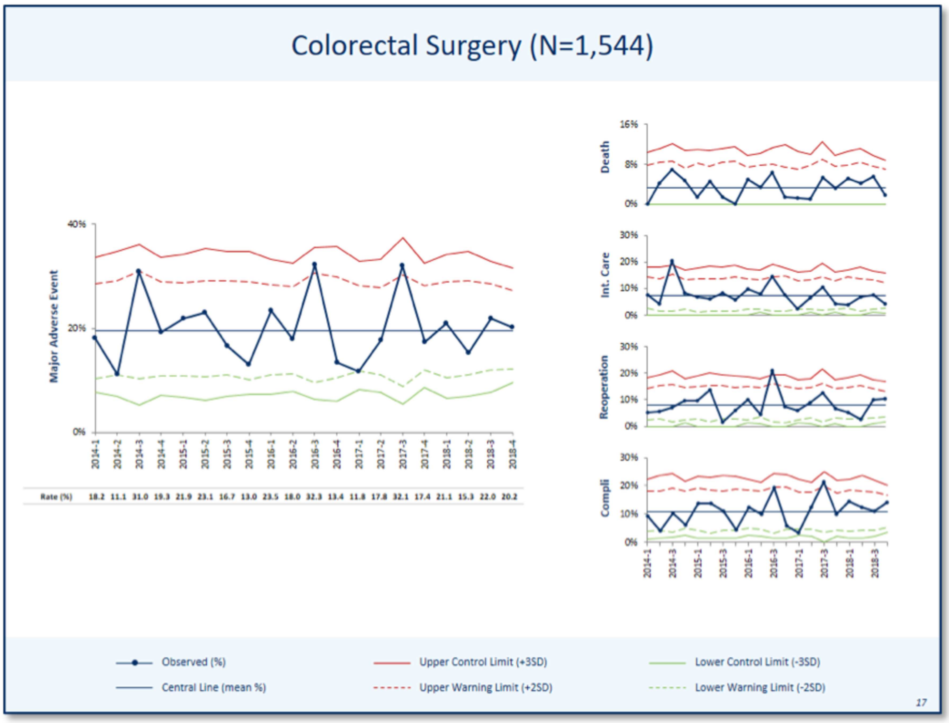
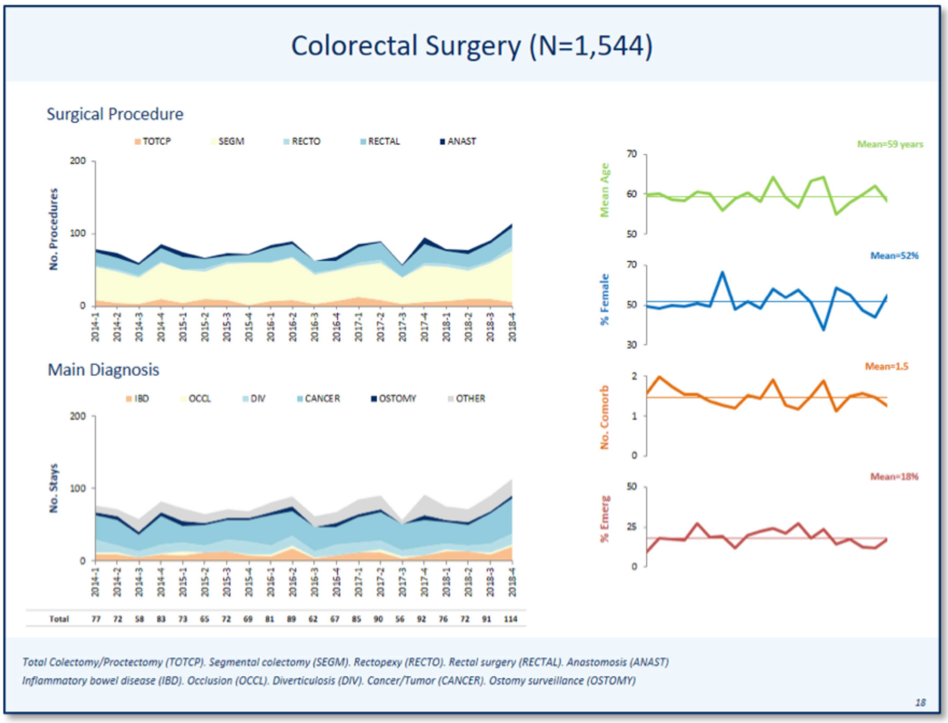
Appendix. Components of Control Chart–Based Program

A tutorial to reproduce the control chart program with slideshows, videos and logbook is available at: http://shewhart.univ-lyon1.fr/. Key elements on how to develop and interpret a p-chart for clinical practice and how to successfully integrate this tool within a comprehensive approach can also be found online at: https://academic.oup.com/intqhc/article/22/5/402/1786749. This includes an open access tutorial accompanied with supplementary material and tools containing fictive data, parameter calculations and chart plotting, so that the reader can easily replicate the method.

Sample slideshow with set of control charts on the colorectal surgery used during team meetings.





Appendix. Compliance with Control Chart–Based Program Implementation

Compliance of each surgical centre with the intervention was measured based on a six-item scoring system, designed prior to the intervention to evaluate the following elements of the intervention: formation of the surgeon duo, participation in all 3 training sessions, logbook updated over 2 years until the end of the intervention, posters displayed in operating room every quarter, team meetings held for interpreting control charts every quarter, at least one concrete action tested for care improvement.

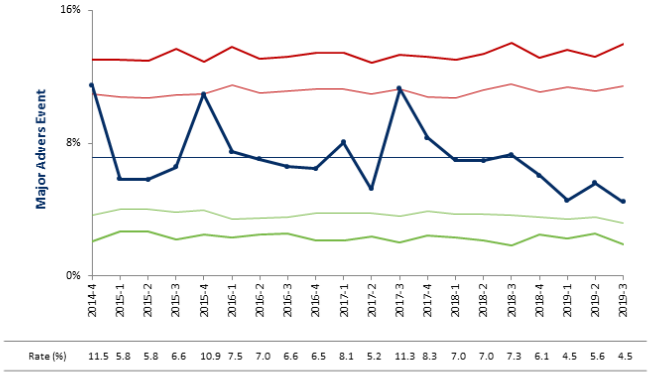
Hospital Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total
Duo formed with a surgeon	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	20
Participation in all 3 training sessions	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1		18
Logbook updated until the end	1	1	1	1	1	1	1	1		1											9
8 posters displayed in operating room	1	1	1	1	1				1									1			7
8 team meetings held	1	1	1	1	1	1	1	1	1		1	1	1								12
At least one improvement action tested	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1	19
Implementation Score	6	6	6	6	6	5	5	5	5	4	4	4	4	3	3	3	3	3	2	2	4.3
Compliance degree	High									Moderate									Poor		

Results of compliance of individual centers with program implementation.

Intervention components	Implementation score (N = 20 hospitals)	Details
Duos formation	Duo formed with a surgeon: 100%	◦ Duos not with 2 surgeons: 60% ◦ Turnover within duo during the study: 20%
Training sessions participation	Participation in all 3 training sessions: 90%	Training sessions: 1 | 2 | 3 ◦ Number of hospitals: 20 | 20 | 18 ◦ Number of participants: 37 | 36 | 33 ◦ Satisfaction score (/10): 8.2 | 8.0 | 8.7 ◦ Investment score (/10): 8.9 | 8.3 | 8.0
Logbook maintenance	Logbook updated until the end: 45%	◦ Mean number of changes recorded per hospital: 19.5 ◦ Type of changes* (n = 390): - Patient: 10% - Organization: 31% - Healthcare worker: 18% - Clinical practice: 9% - Equipment: 10% - Unspecified: 22%
Poster display	8 posters displayed in operating room: 35%	◦ Posters transmitted: 100% ◦ Mean number of posters displayed per hospital: 5.0 ◦ Selfie of duo with the first poster displayed: 100%
Control chart team meetings	8 team meetings held: 60%	◦ Slideshows transmitted: 100% ◦ Mean number of team meeting per hospital: 6.9 ◦ Mean duration of team meeting (min): 53.9 ◦ Mean number of participants per team meeting: 9.3 ◦ Selfie of team meeting: 50%
Improvement plan implementation	At least one improvement plan tested: 95%	◦ Mean number of improvement plans tested per hospital: 3.1 ◦ Types of improvement actions* (n = 61): - Patient (e.g., identity monitoring, abdominal wall surgery work group, post-operative notes for at-risk patients): 6% - Healthcare workers (e.g., specific training for new team members, clarification of surgeon/anaesthesiologist roles, defining the role of the scrub nurse): 13% - Equipment (e.g., anastomosis instrument modification, laparoscopy column modification, audit of operating room materials): 5% - Organization (e.g., programmed prehabilitation, modification in clinical/care pathways, morbidity and mortality reviews with multidisciplinary staff, management of hospital beds, surgical forms): 70% - Clinical practice (e.g., systematic stoma repair, operating room setup, pre-filled prescriptions for compression stockings): 6%

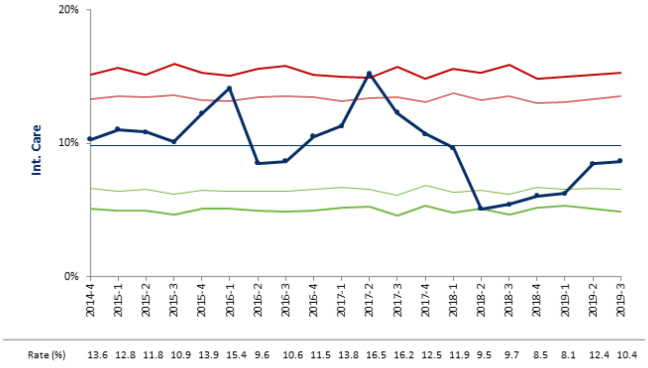
Appendix. Examples of control chart from study with improvement actions made or corrective actions following a special cause variation

Control chart (Hospital A) shows the morbidity and mortality outcomes for all digestive surgeries of a surgical department in the intervention group during the observation and intervention periods. This chart shows a period of time when rates of morbidity and mortality were held relatively constant, at around 8%. The surgical department took advantage of this period of stability to implement and test several improvement actions. First, they reevaluated the surgical and anesthetic responsibilities of the health care professionals in the surgical department. Second, they made several changes related to equipment, including pre-filing prescription for contention stockings and changing the laparoscopy column, and began systematically repairing stomas. Finally, they decided to make an organizational change in the operating room. These changes resulted in a trend towards reduced rates of morbidity and mortality.



Morbidity and mortality for all digestive surgeries (Hospital A)

Control chart (Hospital B) shows the rates of intensive care stays of all digestive surgery patients from a surgical department in the intervention group during the observation and intervention periods. The chart shows that the department experienced special cause variation during the second trimester of 2017. In response, this surgical department implemented several corrective improvement actions. For example, they established that a single surgeon would be in charge of supervising all patients in the intensive care unit. They also decided to no longer systematically send surgical patients to the intensive care unit. In addition, they established an operating room dedicated to treating urgent cases. Together, these changes resulted in improvement in rates of intensive care stays.



Intensive care stay for all digestive surgeries (Hospital B)

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Table S1. Observed number of patients, hospital bed-days and costs by hospital

Hospital group	Hospital ID	No. of patients			No. of hospital bed-days				Hospital costs, €			
		Total			Total	Mean per patient		Total Observed minus Expected in Imp. [a]	Total	Mean per patient		Total Observed minus Expected in Imp. [b]
		Pre-imp. plus Imp.	Pre-imp.	Imp.	Pre-imp. plus Imp.	Pre-imp.	Imp.		Pre-imp. plus Imp.	Pre-imp.	Imp.	
Intervention hospitals	1	3115	1573	1542	21 514	6,8	7,0	321	15 107 475	4749	4953	314 147
	2	3200	1603	1597	26 450	8,5	8,1	-675	23 062 872	7003	7412	653 965
	3	5362	2914	2448	30 775	5,8	5,6	-574	24 927 681	4609	4696	213 522
	4	5646	2834	2812	35 605	6,4	6,2	-482	27 989 238	4835	5081	693 537
	5	4237	1784	2453	38 618	9,9	8,5	-3325	31 119 425	7509	7225	-694 723
	6	2756	1625	1131	17 430	6,6	5,9	-819	12 498 621	4632	4396	-266 462
	7	3185	1143	2042	15 907	6,3	4,2	-4293	10 173 638	3653	2938	-1 459 750
	8	3768	2049	1719	34 265	8,7	9,5	1366	27 454 245	6679	8010	2 287 263
	9	4687	2311	2376	29 648	6,6	6,1	-1206	24 373 793	5322	5082	-570 120
	10	4446	2073	2373	35 013	8,5	7,3	-2901	26 953 381	6481	5697	-1 860 523
	11	3247	1751	1496	21 508	6,7	6,6	-166	7 954 759	2419	2486	101 364
	12	2579	1290	1289	13 768	5,7	5,0	-916	10 658 637	4293	3973	-412 283
	13	3856	1964	1892	22 080	5,7	5,8	210	17 678 547	4367	4811	839 396
	14	5705	2768	2937	47 648	8,8	7,9	-2572	41 037 916	7593	6817	-2 278 996
	15	4322	2177	2145	24 728	5,8	5,7	-160	22 877 218	5278	5309	65 470
	16	2693	1409	1284	19 218	7,4	6,9	-648	16 036 247	5912	6001	114 127
	17	2843	1423	1420	17 073	6,3	5,7	-818	11 883 411	4188	4172	-22 387
	18	3748	2012	1736	19 908	5,2	5,5	460	9 048 086	2381	2452	123 718
	19	2815	1465	1350	20 025	7,2	7,1	-120	15 035 316	5288	5399	149 980
	20	2837	1411	1426	18 379	6,6	6,4	-211	16 588 248	5902	5793	-156 427
	Total	***75 047***	***37 579***	***37 468***	***509 560***	***7,0***	***6,6***	***-14633***	***392 458 755***	***5225***	***5234***	***326 719***
Control hospitals	21	6497	3404	3093	41 310	6,5	6,2	-989	29 828 783	4537	4651	352 120
	22	5292	2785	2507	37 184	7,1	7,0	-164	27 243 888	5128	5170	105 459
	23	4822	2418	2404	39 323	8,5	7,8	-1901	30 000 145	6242	6201	-98 198
	24	4469	2245	2224	38 189	8,9	8,2	-1367	28 955 945	6461	6498	80 819
	25	2092	1161	931	12 760	6,6	5,5	-994	8 406 055	4120	3891	-213 806
	26	4349	2252	2097	31 680	7,1	7,4	667	27 242 142	6259	6269	21 674
	27	2253	1221	1032	13 078	5,9	5,7	-270	5 955 769	2501	2812	320 303
	28	2696	1324	1372	17 143	6,9	5,9	-1415	6 590 689	2637	2259	-517 699
	29	3235	1713	1522	24 770	8,1	7,1	-1459	18 893 144	6113	5533	-882 954
	30	3343	1741	1602	29 552	8,4	9,4	1604	23 198 054	6391	7535	1 833 846
	31	3504	1856	1648	21 234	6,3	5,8	-789	11 553 276	3478	3093	-633 880
	32	7211	3722	3489	64 978	9,2	8,8	-1157	57 815 406	8099	7931	-583 022
	33	4988	2810	2178	30 271	5,8	6,4	1378	16 387 378	3179	3422	528 149
	34	2627	1365	1262	15 391	6,3	5,4	-1093	7 842 732	3083	2880	-255 785
	35	4280	2306	1974	26 264	5,9	6,4	1083	18 235 245	4064	4490	840 204
	36	5292	2494	2798	35 738	7,0	6,5	-1416	31 221 821	5899	5900	3067
	37	2164	1202	962	14 191	6,2	6,9	667	4 974 241	2221	2396	167 809
	38	3645	1777	1868	26 135	7,2	7,1	-168	19 976 333	5287	5665	706 524
	39	4796	2355	2441	38 838	8,1	8,0	-245	29 601 817	6193	6152	-100 463
	40	2760	1397	1363	16 845	6,4	5,8	-764	12 832 787	5001	4289	-970 826
	Total	***80 315***	***41 548***	***38 767***	***574 874***	***7,2***	***7,1***	***-6984***	***416 755 649***	***5146***	***5235***	***3 452 065***
Total		***155 362***	***79 127***	***76 235***	***1 084 434***	***7,1***	***6,8***	***-21 945***	***809 214 404***	***5 184***	***5 234***	***3 878 672***

Pre.imp, pre-implementation period; Imp., Implementation period.

[a] Difference = (Total observed No. of bed-days in Implementation period) – (Total expected No. of bed-days in Implementation period), with: Total expected No. of bed-days in Implementation period = (Total observed No. of patients in Implementation period) * [(Total observed No. of bed-days in Pre-implementation period) / (Total observed No. of patients in Pre-implementation period)]

[b] Difference = (Total observed hospital costs in Implementation period) – (Total expected hospital costs in Implementation period), with: Total expected hospital costs in Implementation period = (Total observed No. of patients in Implementation period) * [(Total observed hospital costs in Pre-implementation period) / (Total observed No. of patients in Pre-implementation period)]

Appendix. Models specifications

To model the mean number of hospital bed-days per patient within 30 days following surgery and the mean hospital costs reimbursed for this care per patient by the insurer, we computed generalized linear mixed models (GLMM) with a log link and a random intercept for hospitals.

General mathematical formulation of GLMM

$$Y_i|\boldsymbol{u} \sim indep.\, f_{Y_{i|u}}(y_i|\boldsymbol{u}),$$
$$f_{Y_{i|u}}(y_i|\boldsymbol{u}) = exp\left\{\frac{[y_i\gamma_i - b(\gamma_i)]}{\tau^2} - c(y_i,\tau)\right\},$$
$$E[Y_i|\boldsymbol{u}] = \mu_i,$$
$$g(\mu_i) = x_i'\beta + \boldsymbol{z}_i'\boldsymbol{u},$$
$$\boldsymbol{u} \sim f_U(u),$$

with the following specifications:
- the distribution of Y_i from an exponential family (in this case the distribution is assumed to hold conditional on the random effects $\boldsymbol{u}$),
- a link function, $g(\cdot)$ is applied to the conditional mean of Y_i given $\boldsymbol{u}$ to obtain the conditional linear predictor,
- the linear predictor is assumed to consist of two components, the fixed effect portion, described as $x_i'\beta$ and the random effects portion, $\boldsymbol{z}_i'\boldsymbol{u}$, for which a distribution is assigned to $\boldsymbol{u}$**.**

[from McCulloch, C. E. *Generalized Linear Mixed Models*. (IMS, 2003).**]**

Equation of the models used for the number of hospital bed-days and costs

Let y_{ij} represent the number of hospital bed-days or costs for patient *j* at hospital *i* within the 30-days following the surgery.
For the hospital bed-days, y_{ij} follows a negative-binomial distribution with a mean expected number of hospital bed-days of μ_{ij}.
For the hospital costs, y_{ij} follows a gamma distribution with a mean expected hospital cost of μ_{ij}.
Independent variables incorporated in the models were the period and the study group with their interaction, the death status and the patient expected number of hospital bed-days or costs consumption with their interaction.

$$\begin{aligned}\ln(\mu_{ij}) = {} & \beta_0 + \boldsymbol{u_{0i}} + \beta_1\mathrm{POST}_{ij} + \beta_2\mathrm{INTER}_{ij} + \beta_3\mathrm{POST}\times\mathrm{INTER}_{ij} + \beta_4\mathrm{DEATH}_{ij} + \beta_5\mathrm{SCOREQ2}_{ij} + \beta_6\mathrm{SCOREQ3}_{ij} \\ & + \beta_7\mathrm{SCOREQ4}_{ij} + \beta_8\mathrm{DEATH}\times\mathrm{SCOREQ2}_{ij} + \beta_9\mathrm{DEATH}\times\mathrm{SCOREQ3}_{ij} + \beta_{10}\mathrm{DEATH}\times\mathrm{SCOREQ4}_{ij}\end{aligned}$$

β_0 the fixed intercept
$\boldsymbol{u_{0i}}$ the random intercept for hospital i, $\sim N(0,\psi)$
POST_{ij}=1 if implementation period and 0 if pre-implementation period
INTER_{ij}=1 if intervention group and 0 if control group
DEATH_{ij}=1 if deceased and 0 if alive
$\mathrm{SCOREQ2}_{ij}$ =1 if patient expected number of bed-days consumption quartile 2 and 0 otherwise
$\mathrm{SCOREQ3}_{ij}$ =1 if patient expected number of bed-days consumption quartile 3 and 0 otherwise
$\mathrm{SCOREQ4}_{ij}$ =1 if patient expected number of bed-days consumption quartile 4 and 0 otherwise
$\beta_{k,k=1,..10}$ the fixed-effect regression coefficients

The ratio of rate ratios (RRR) or ratio of cost ratios (RCR) was estimated by exponentiating β_3, the regression coefficient corresponding to the interaction between POST_{ij} and INTER_{ij}.

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Appendix. Marginal standardization method

We calculated standardized rates of hospital bed-days and standardized hospital costs for each group and period using estimated regression coefficients obtained from generalized linear mixed models (GLMM) and a marginal standardization method inspired from Austin et al.[1] and Muller et al.[2].

We computed the predicted number of hospital bed-days and costs for each patient if the whole study population were in the Intervention hospitals during the Pre-implementation period, then if the whole study population were in the Control hospitals during the Pre-implementation period, then if the whole study population were in the Intervention hospitals during the Implementation period, and then if the whole study population were in the Control hospitals during the Implementation period.

To do so, after performing the GLMM, we set the study group to Intervention and the period to Pre-implementation for every patient, and used the regression coefficients to calculated predicted number of hospital bed-days and costs for every patient at their observed confounder pattern and newly assigned exposure value (hospital group and study period). Then we averaged these predicted number of hospital bed-days and costs across the study cohort to obtain the standardized rates of hospital bed-days and standardized hospital cost in Intervention hospitals during the Pre-implementation period. We proceeded in the same way to compute the standardized rates of hospital bed-days and costs in Control hospitals during the Pre-implementation period, in Intervention hospitals during the Implementation period, and in Control hospitals during the Implementation period.

Use of these standardized rates of hospital bed-days and costs allowed us to compare economic outcomes between 4 populations whose only difference is the exposure (hospital group and study period).

[1] Austin, P. C. Absolute risk reductions, relative risks, relative risk reductions, and numbers needed to treat can be obtained from a logistic regression model. *J. Clin. Epidemiol.* **63**, 2–6 (2010).
[2] Muller, C. J. & MacLehose, R. F. Estimating predicted probabilities from logistic regression: different methods correspond to different target populations. *Int. J. Epidemiol.* **43**, 962–970 (2014).

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Table S2. Comparison of economic outcomes by hospital group including patients with missing household income

Economic Outcomes	Intervention Hospitals			Control Hospitals			Intervention vs Control Hospitals	
	Pre-implementation	Implementation	Implementation vs Pre-implementation	Pre-implementation	Implementation	Implementation vs Pre-implementation		
	Mean Observed Number Per Patient		Adjusted Rate or Cost Ratio (95% CI)	Mean Observed Number Per Patient		Adjusted Rate or Cost Ratio (95% CI)	Adjusted Ratio of Rate or Cost Ratio (95% CI)	***P* value**
Number of hospital bed-days	7.0	6.6	0.91 (0.90-0.92)	7.2	7.1	0.94 (0.93-0.95)	0.97 (0.95-0.98)	< .001
Hospital costs, €	5226	5237	0.95 (0.95-0.96)	5132	5239	0.96 (0.96-0.97)	0.99 (0.98-1.00)	.049

A total of 156 133 patients were included in the analysis. Missing household incomes for 771 patients were imputed by the mean household income of patients with available household income in the same hospital group (Intervention/Control) and period (Pre-implementation/Implementation). Adjusted rate or cost ratios were estimated using multivariable generalized linear mixed models with a log link to compare economic outcomes between pre-implementation and implementation periods in intervention and control hospitals. A negative binomial distribution was used to model the mean number of hospital bed-days per patient within 30 days following surgery, and a gamma distribution to model mean hospital costs reimbursed for this care per patient by the insurer. Adjusted ratios of rate ratios (RRR) or ratios of cost ratios (RCR) captured the control chart impact by comparing the change in outcomes from the pre-implementation to implementation periods between the intervention and control hospitals based on a difference-in-difference approach. A RRR or RCR value less than unity indicated improvement caused by control charts in intervention versus control hospitals. Estimates with corresponding 95% confidence interval (95% CI) considered clustering of patients at the hospital level. Outcomes were adjusted for the patient expected number of health care consumption, death status within 30 days following surgical procedure, and their interaction. The patient expected number of health care consumption was introduced in models as a categorical variable (quartiles), and considered age, sex, presence of comorbidities, emergency admission, date and operative procedure, main diagnosis, surgical procedure complexity, median household income for patient-level covariates, and status for hospital-level covariates. €1.00 (£0.83; $1.09).