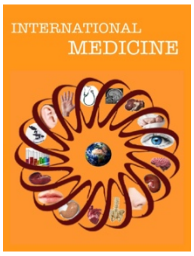

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Short Communication

Extended application of statistical process control-quantitative risk assessment techniques to monitor surgical site infection rates

Mostafa Essam Ahmed Eissa

Department of Microbiology and Immunology, Cairo University, Cairo, Egypt

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Abstract

Surgical wound infections are major challenges affecting the health and even the life of patients subjected to invasive operations in hospitals. Healthcare providers should ensure the appropriate quality control of surgical site infection (SSI). World Health Organization (WHO) provides a comprehensive global database record of SSI. Monitoring of the trend of SSI rate and magnitude using statistical process control (SPC) tools would deliver useful information about the previous, current, and expected behavior and pattern of the inspected quality characteristic. The degree of compliance with good practices guidelines and rules (GXP) and the improvement achieved or required might be assessed and quantified using Shewhart or process-behavior trending charts. The following study demonstrates the application of SPC analysis using commercial software packages in the assessment of SSI in selected cases of countries from the WHO dataset.

Keywords: ANOVA, European Union, surgical wound infection, World Health Organization

Introduction

Infections related to surgical procedures are a global challenge that may impact a patient's health and may even threaten life in extreme cases [1]. Control measures of surgical site infection (SSI) are being actively sought to contain it. These measures should minimize the contamination of surgical wounds from both endogenous and exogenous microorganisms [2]. The worldwide efforts to set standards for control of SSI are supported by WHO guidelines, resources, tools, and database records collected from different nations [3-5].

The present study demonstrates the application of statistical process control (SPC) on SSI rates trends of selected nations from WHO records as could be shown in Table 1, which lists the categorization and the abbreviation code for each country [5]. It should be noted that in this SSI work Tajikistan (TJK) is listed alone and as part of the Central Asian Republics Information Network (CARINFONET) database record [5].

Address for Correspondence: Mostafa Essam Ahmed Eissa, Department of Microbiology and Immunology, Cairo University, Cairo, Egypt.
E-mail: mostafaessameissa@yahoo.com

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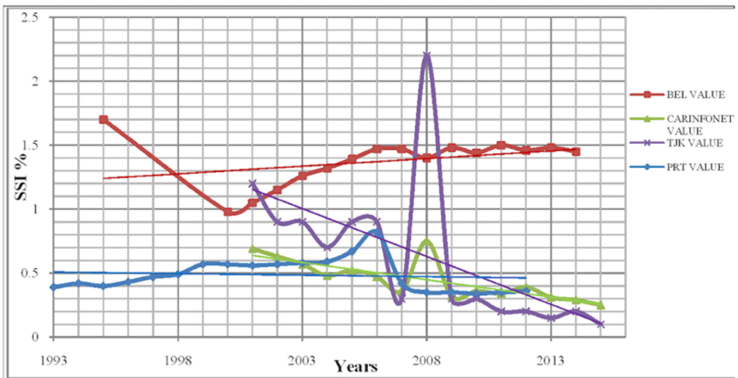
SSI Pattern Monitoring Using Statistical Software

It could be observed that the general trend line of SSI % was toward decreasing rates except for Belgium (BEL) which showed a gradual increase. The average SSI value was low for CARINFONET region and relatively high for BEL despite greater annual variations that could be seen in TJK as could be seen from Figure 1.

Table 1. WHO record for SSI rates of the selected countries under investigation [5]

Country group full name†	ISO 2	WHO Code/ ISO 3	WHO European Region	Members of the European Union	Members of the European Union before May 2004 (EU15)	Members of the European Union after May 2004 (EU13)	Commonwealth of Independent States	Central Asian Republics Information Network members (CARINFONETᴪ)
Belgium	BE	BEL	yes	yes	yes	no	no	no
Portugal	PT	PRT	yes	yes	yes	no	no	no
Tajikistan‡	TJ	TJK	yes	no	no	no	yes	yes

ᴪCARINFONET consists of five nations: Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, and Uzbekistan.
‡Independent SSI % record from CARINFONET is available for TJ.
†Data source: https://gateway.euro.who.int/en/datasets/european-health-for-all-database/.



Number of values	PRT VALUE	TJK VALUE	CARINFONET VALUE	BEL VALUE[ς]
Mean ± Std. Deviation	0.49 ± 0.13	0.63 ± 0.57	0.45 ± 0.15	1.4 ± 0.18
Std. Error of Mean (SEM)	0.029	0.15	0.040	0.046
D'Agostino & Pearson omnibus normality test				
K2	4.1	11	1.7	2.8
P value	0.1291	0.0037	0.4246	0.2419
Passed normality test (α =0.01)?	Yes	No	Yes	Yes
P value summary	ns	**	ns	ns
Shapiro-Wilk normality test				
W	0.90	0.81	0.92	0.89
P value	0.0347	0.0044	0.2276	0.0515
Passed normality test (α =0.01)?	Yes	No	Yes	Yes
P value summary	*	**	ns	ns
KS normality test				
KS distance	0.17	0.25	0.18	0.22
P value	0.1585	0.0104	0.2000	0.0372
Passed normality test (α=0.01)?	Yes	Yes	Yes	Yes
P value summary	ns	*	ns	*

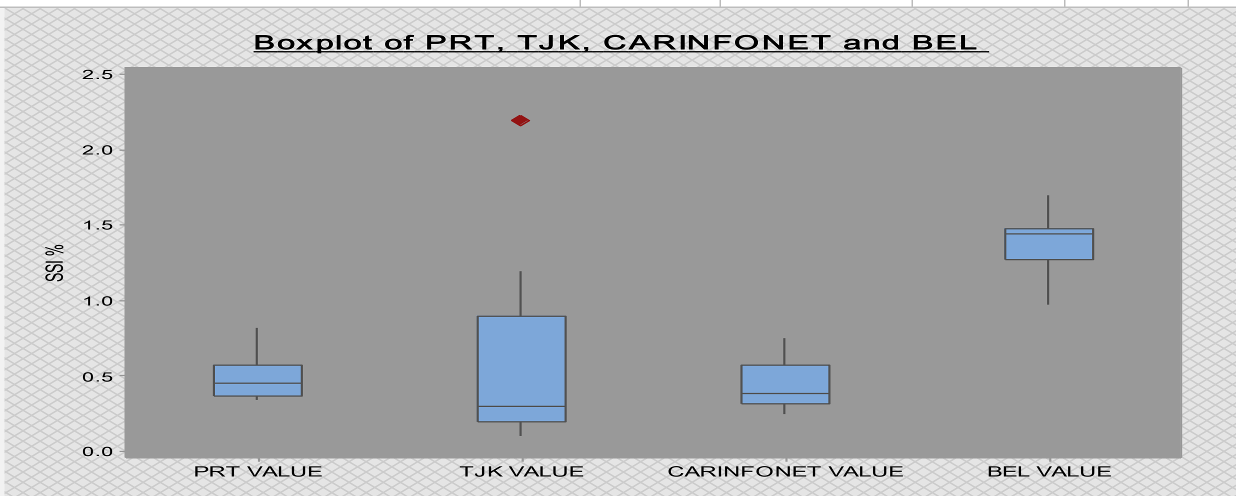
Figure 1. Time series plot showing general trend lines of SSI for the four selected subjects of the study appended with descriptive statistics (Data generated using GraphPad Prism for Windows version 6.01/Microsoft Office Excel).
ns: Not Significant KS: Kolmogorov-Smirnov Source: WHO[5] [ς]No results were found between the years 1995 and 2000

Statistical software (GraphPad Prism for Windows version 6.01) analysis showed that TJK data showed significant skewness from Gaussian distribution at a 99% confidence level and passed only Kolmogorov-Smirnov (KS) normality test while other groups passed all normality tests. Spearman correlation showed weak (BEL with PRT and TJK), moderate (BEL with CARINFONET and PRT with TJK and CARINFONET), and very strong (normally, TJK with CARINFONET) levels of relations between datasets [6].

On the other hand, histograms of Figure 2 illustrate data distribution showing their degree of distortion from the bell-shape of the normal distribution spreading. Moreover, Box plot diagram shows the difference between general trend, spreading, distortion in distribution and outlier point(s) (evident in TJK only marked by a red colored single point) of SSI rates. One-Way ANOVA at α=0.05 in Table 2 shows that BEL SSI rate is significantly higher than other groups which are supported by Box-and-Whisker plot. When TJK record is included with CARINFONET SSI rate, the net result is lower mean value for SSI percent and minimal data spreading without outliers. The details of the report generated using a statistical program (GraphPad Prism for Windows version 6.01) are numerically presented in Table 2.

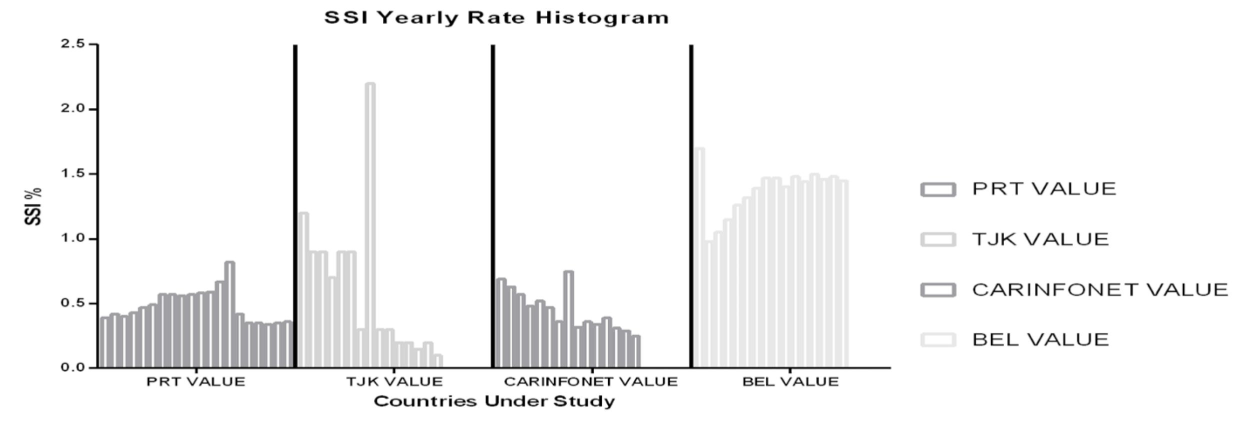
Table 2. Box-and-Whisker plot and One-Way ANOVA test showing data spreading, skewness, and outlier(s) (marked as a red dot) combined with the assessment of the significance of variation between SSI percent of each group (Data generated using GraphPad Prism for Windows version 6.01/Minitab® version 17.1.0)

One-Way ANOVA					
Significance level (Alpha)	0.05				
Tukey's multiple comparisons test	Mean diff.	95% CI of diff.	Significant?	Summary	DF
PRT VALUE vs. TJK VALUE	-0.15	-0.42 to 0.13	No	ns	62
PRT VALUE vs. CARINFONET VALUE	0.036	-0.24 to 0.31	No	ns	62
PRT VALUE vs. BEL VALUE	-0.89	-1.2 to -0.62	Yes	****	62
TJK VALUE vs. CARINFONET VALUE	0.18	-0.11 to 0.47	No	ns	62
TJK VALUE vs. BEL VALUE	-0.75	-1.0 to -0.46	Yes	****	62
CARINFONET VALUE vs. BEL VALUE	-0.93	-1.2 to -0.64	Yes	****	62



Test details	Mean diff.	SE of diff.	n1	n2	q
PRT VALUE vs. TJK VALUE	-0.15	0.10	20	15	2.0
PRT VALUE vs. CARINFONET VALUE	0.036	0.10	20	15	0.50
PRT VALUE vs. BEL VALUE	-0.89	0.10	20	16	12
TJK VALUE vs. CARINFONET VALUE	0.18	0.11	15	15	2.3
TJK VALUE vs. BEL VALUE	-0.75	0.11	15	16	9.7
CARINFONET VALUE vs. BEL VALUE	-0.93	0.11	15	16	12

ns: Not Significant, CI: Confidence Interval, DF: Degree of Freedom, SE: Standard Error, Raw data source: WHO [5]



Two-tailed correlation\P	PRT	TJK	CARINFONET	BEL
PRT		-0.55	-0.52	0.26
TJK	0.02778845		0.92	-0.38
CARINFONET	0.04517695	2.995682e-006		-0.40
BEL	0.3284539	0.1393091	0.1383545	Raw data: WHO[5]

Figure 2. Histogram showing SSI rates for four WHO data records along with correlation matrix at a 95 % confidence interval (Data generated using GraphPad Prism for Windows version 6.01).

Laney modified attribute control charts were constructed using SPC software and the methods were detailed and described through Minitab® version 17.1.0 [7,8]. Laney process-behavior charts are more accurate in isolating assignable-cause variations from common-cause variations when data do not show compliance with the presumed distribution required for ordinary trending charts [9]. Attribute control charts present SSI rates as the number of cases per 10,000 patients and the red points represent special-cause out-of-control SSI years. Warning signals above the midline of the mean value (green solid line) are required to be investigated to set further measures to control SSI. In the same line, red dots below U' line provide a good opportunity for improvements and to learn from it where SSI % at minimum values (Figure 3).

Discussion

Despite the general stability of SSI % for PRT, there was unusual aberrant spiking in two successive years due to possible extraneous factors that require investigation to set better control. A similar situation could be found with TJK (and normally linked to CARINFONET region trend) at one year. However, in case of BEL, the drop from high SSI value to low rates was campaigned by a gradual increase through the following years and the shift in the process means to reach a new higher value. Thus, a continuous update of data is required to elucidate the new drift in the balance and to verify the process stability. However, it would be desirable to bring SSI rates to the downside again to maintain the infection risk at minimum values in hospitals. Laney modified control charts have been applied in various fields in the healthcare industry including pharmaceutical processes [10-12]. The ease with which trending charts could be applied will facilitate on-time process monitoring and control to guard against any possible excursions that may ruin money and efforts in any industry. The current work shows that further improvements and GXP measures are required to ensure better control over infections in hospitals that are stemmed from surgical wound contamination by microbial cells. Years of SSI rate excursion should be reviewed to analyze the root causative factors to set protective measures for patient health and life. Also, the stability of SSI percent from year to year is indicative for the adequacy of the countermeasures against microbial intrusion into the surgical wound. Other factors should not be overlooked such as the significant rise in the number of admitted individuals to hospitals, ecological and demographical changes impact.

Simple risk assessment for SSI from control charts

Simple and fast risk analysis method could be derived from control charts parameters by considering multiplication of both means (as a severity factor) and upper control limit (as a brink of excursion). The multiplication will amplify small differences which will expose the significance between the comparisons. For instance, SSI risk for BEL (2.11) is the highest followed by TJK (1.04) then CARINFONET (0.33) and PRT (0.30).

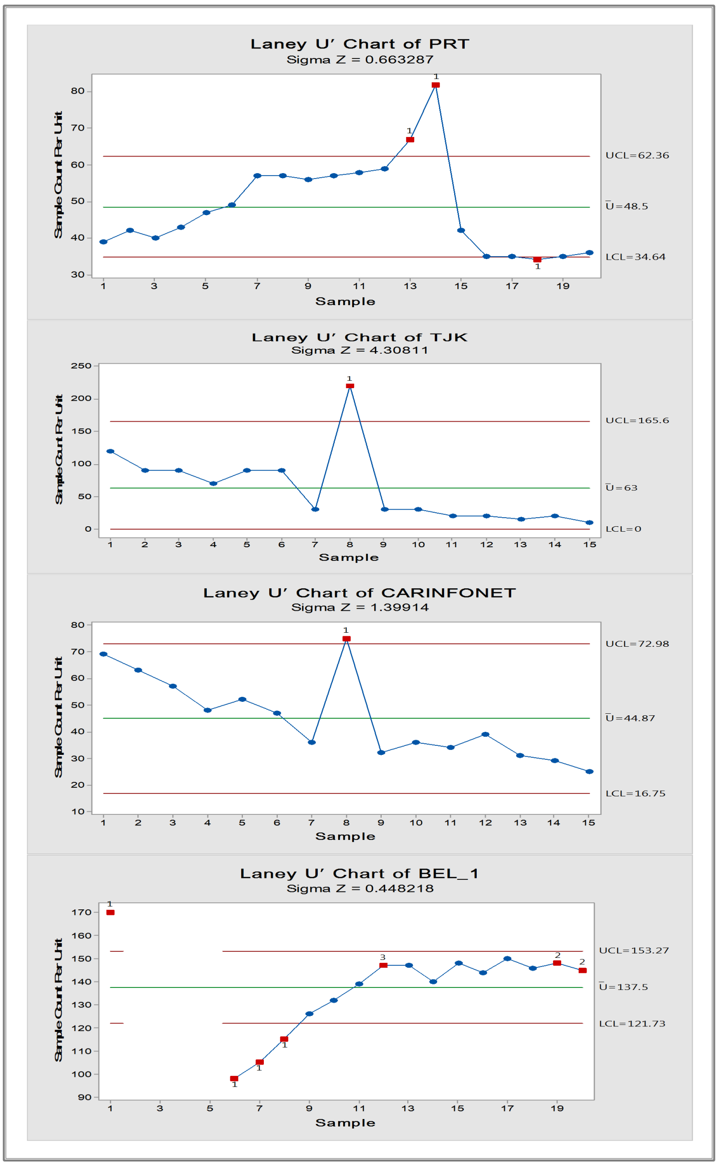


Figure 3. Laney attribute process-behavior control charts for SSI rates (gap due to discontinuation of the record during that period) (Data generated using Minitab® version 17.1.0, Raw data source: WHO [5]).

Conclusion

SPC tools are useful for monitoring global records of SSI rates to monitor the past and current states of control and to investigate excursions to set corrective actions and preventive actions (CAPA). Nevertheless, the area of improvements could be spotted from the process-behavior charts to provide better control measures on microbial infections within healthcare facilities in order to stabilize SSI trends at low levels.

Conflict of interest

None to declare.

Funding

Not applicable.

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