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Research article

APPLICATION OF STATISTICAL PROCESS CONTROL ON ANALYSIS OF SURGERY-RELATED INFECTION RECORD: AN EXTENDED STUDY OF THREE SELECTED COUNTRIES USING STATISTICAL SOFTWARE

Mostafa Essam Eissa

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

Abstract

Background: *Contamination of surgical wound by microorganisms impacts patients' health and may result in mortality. Due to the global importance of the surgical site infection (SSI), a database record is set by the World Health Organization (WHO) to monitor SSI rates from different nations.*

Objective: *The current work aimed to establish timely monitoring of SSI rates using commercial statistical software packages. Statistical process control (SPC) will provide insight into the yearly SSI trends of three countries. SPC measures the adequacy, effective GXP implementation and stability of containment for SSI. Moreover, two types of process-behaviour Charts were compared in the visualizing SSI rates.*

*Corresponding author's E-mail: mostafaessameissa@yahoo.com

Materials and methods: *Statistical programs were used to process data from WHO records of SSI yearly percents from three selected nations, namely: Hungary (HUN), Ireland (IRL) and Kyrgyzstan (KGZ) which are different geographically and demographically. Constructed control charts for each dataset were Laney-modified attribute and Individual-Moving Range (I-MR) charts.*

Results: *The low-correlated SSI rate data showed a significant degree of normality with IRL figures showing a relatively higher trend. Both Laney attribute and (I) portion of I-MR charts agree in both control limits and most of the alarms. Nevertheless, the variable chart has extra sensitivity to other types of warning signals.*

Discussion: *SPC can spot data pattern, spreading and distribution. Both types of control charts can be used with variable-type may show the ability to assess the stability of the inspection characteristic variability through the MR chart.*

Conclusion: *SPC tools provide effective guidance for the control of SSI.*

Keywords: SSI; SPC; Laney; I-MR; Process-behaviour charts

Introduction

Every year, a huge number of surgical operations are performed, and the record is growing progressively. However, one of the most annoying challenges in any healthcare facility is the intrusion of microorganisms in the normally sterile body cavities. The contamination of the surgical wound by microbes which results in the infection of the affected area is called surgical site infection (SSI) and may lead to complications that threaten patients' health and even life resulting in morbidity and mortality (Eissa, 2018).

Due to this serious challenge, the World Health Organization (WHO) has established an active monitoring database system to collect global records from different nations worldwide about SSI rates over years of close surveillance (Allegranzi *et al*., 2016; WHO, 2017). The control of the cases SSI is linked to the measures that are set to limit microbial intrusion into the surgical wound in the operation theatre. This, in turn, is associated with the degree of compliance with good practices, collectively called GXP (Eissa, 2018b).

Statistical process control (SPC) tools provide mean for assessing the inspection properties quantitatively and visual measure for the process efficiency and stability (Montgomery, 2009). With this respect, SPC can evaluate the current and the future state of SSI situation and determine its compliance to control measures as demonstrated similarly before in other researches in the healthcare industry such as in pharmaceutical facilities to assess specific properties of medicinal products or efficacy of air quality and water in the firm (Eissa *et al.*, 2016; Essam Eissa, 2017 and Eissa, 2018a).

The present study aimed to investigate the use of SPC in monitoring trends in SSI rates from three selected countries — that is geographically and demographically different — in WHO records of global surgical wound infections. Also, the study would show the past and present situation quantitatively of SSI rates to predict the future state. Nevertheless, the process stability, GXP and the control measures for containment of SSI should not be overlooked and they could be predicted through control charts. Moreover, the current work will investigate the difference between the applications of two types of process-behaviour charts for the cases under investigation. This case evaluation is part of a project that covers other nations monitored by WHO for SSI yearly percent.

Materials and Methods

Data and source for the subject of study

Global record of SSI rates was monitored from WHO Website (European Health Information Gateway, 2019). From this site, data of three selected countries - which are different geographically and demographically - was obtained. Information about these countries could be found in Table 1 (European Health Information Gateway, 2019).

Box-and-Whisker diagram, Descriptive statistics, One-Way ANOVA and Correlation Matrix

Statistical analysis - including normality tests - was generated using statistical program GraphPad Prism for Windows version 6.01 and it was used according to the manual of software (GraphPad Prism User Guide, 2014; GraphPad Statistics Guide, 2014). Data analysis was done for SSI % for three nations: Hungary (HUN), Ireland (IRL) and Kyrgyzstan (KGZ).

Histograms, diagnostic tests and control charts

SPC tools were applied using software Minitab® version 17.1.0 and it was used according to its detailed user guide (Minitab®, 2014). The program was used for SSI rates of HUN, IRL and KGZ. Attribute control charts express SSI rates as the number of cases per 10,000. While Individual-Moving Range (I-MR) process-behaviour charts demonstrate raw data as a percent.

Results and Discussion

HUN showed narrower data dispersion with lower values of SSI percents if compared with KGZ and IRL which demonstrated relatively higher figures of SSI % with greater spreading as could be seen in Table 2 where Box plot diagram is expressed numerically. However, distortion of normal data scattering of Box plot is more evident with KGZ. Moreover, no year points — showing outlier SSI rates — could be seen in the diagram. In addition, Box-and-Whisker plot is important as in the current analysis of data to show

Table 1: Country group mapping according to WHO record

Country short name	Hungary	Ireland	Kyrgyzstan
ISO 2 abbreviation	HU	IE	KG
ISO 3 abbreviation	HUN	IRL	KGZ
WHO code	HUN	IRE	KGZ
WHO European Region	√	√	√
Members of the European Union before May 2004 (EU15)	X	√	X
Members of the European Union after May 2004 (EU13)	√	X	X
Commonwealth of Independent States (CIS)	X	X	√
Central Asian Republics Information Network members (CARINFONET)	X	X	√

minimum, maximum, median, upper quartile (Q3 = 75th percentile or centile), upper quartile (Q1 = 25th percentile or centile) and interquartile range (IQR) (Segonds-Pichon, 2017).

Statistical comparison between the three groups of SSI rates was done and shown in Table 3. The analysis demonstrated a significant difference between IRL and both KGZ and HUN, where it demonstrated a truly higher yearly trend. The parametric test was done using One-Way ANOVA with Tukey's multiple comparisons as a follow-up test at 95 % confidence interval (CI) and q = sqrt(2)*D/SED, where D = the difference between the two means and SED = the standard error of that D (Tukey and Dunnett methods, 2017).

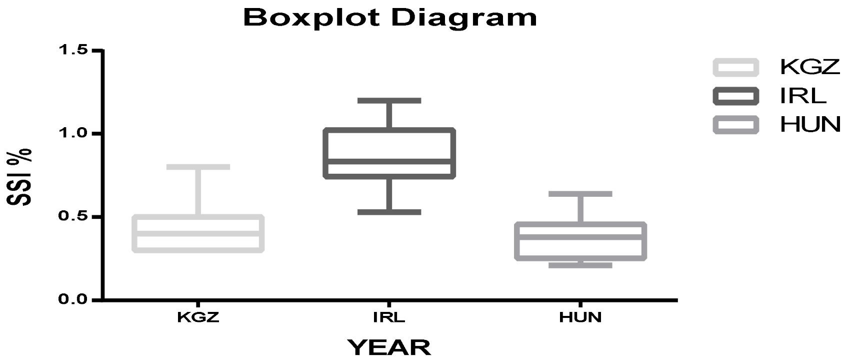
Table 4 shows the degree of association between the patterns of SSI yearly percents for the three nations under investigation. Parametric two-tailed correlation matrix demonstrated weak correlations except moderate one between HUN and IRL (Wilson, 2009). As P value is getting lower, the greater the chance to exclude the possibility of the association between two variables (SSI %) due to random selection (GraphPad Statistics Guide, 2017). Thus, these results might indicate a significant difference between the conditions and the measures taken to control SSI.

Descriptive statistics in Table 5 demonstrate the average value for each dataset along with quantifying variability (standard deviation: SD) and precision (Standard Error of the Mean: SEM) of the means (GraphPad Statistics Guide, 2017). The figures are in the following decreasing order: IRL > KGZ > HUN. The first test of normality is the recommended one, but the last one is now of little value (Dallal and Wilkinson, 1986; D'Agostino, 1986 and Royston, 1995). Interestingly, K-S test is still provided by the program (Choosing a normality test, 2017). KGZ record demonstrates the greatest deviation from the null hypothesis of Gaussian distribution (D'Agostino, 1986).

Histograms of SSI rates of the three countries could be seen in Fig. 1. The apparently non-unimodal distorted shapes of distributions may be indicative for more than single process or operation in place and/or procedures or conditions for control of SSI rates that may be changing with time. This is not strange in view of that bimodal distribution has been reported previously by some researchers in infectious disease spreading in society (Feng *et al*., 2006 and Nunn*et al*., 2011). Interestingly, KGZ showed cut-off gaps due to

Table 2: Quantitative assessment of data spreading and skewness of SSI % for three selected countries along with box plot diagram (Generated using GraphPad Prism for Windows version 6.01)

Quantitative Assessment for Data Dispersion	KGZ	IRL	HUN



Minimum	0.300	0.530	0.210
25% Percentile	0.300	0.743	0.253
Median	0.400	0.835	0.380
75% Percentile	0.500	1.023	0.458
Maximum	0.800	1.200	0.640
10% Percentile	0.300	0.665	0.220
90% Percentile	0.741	1.125	0.578
Lower 95% CI of mean	0.379	0.797	0.325
Upper 95% CI of mean	0.518	0.948	0.437
Lower 95% CI of median	0.300	0.750	0.260
Upper 95% CI of median	0.500	1.020	0.440

CI: Confidence Interval which percent gives estimation about the possibility that this range includes the true value. Percentile: Normalized ranks which give relative standing position of each individual value in a group.

Table 3: One-Way ANOVA comparing SSI rates for three countries using statistical software (Generated using GraphPad Prism for Windows version 6.01)

Tukey's multiple comparisons test (α 0.05)	KGZ vs. IRL	KGZ vs. HUN	IRL vs. HUN
Mean Diff.	-0.42	0.07	0.49
95% CI of diff.	-0.53 to -0.31	-0.04 to 0.18	0.38 to 0.60
Significant?	Yes	No	Yes
Summary	****	ns	****
Number of years in each group	22	DF	63
SE of diff.	0.04582	0.04582	0.04582
Q	13.09	2.09	15.18

DF: Number of degrees of freedom α: Significance level CI: Confidence Interval ns: Not Significant SE: Standard Error

isolated values of SSI % that stand far from the usual trend. Before constructing an attribute control charts, a test of fitness of ordinary-type of the process-behaviour chart was conducted using SPC program and it showed unsuitability of the conventional type of attribute charts as could be seen in Fig. 2. Hence, Laney-modified charts were selected (Minitab® 18 Support, 2017).

Like the current situation, the advantage of Laney control chart has been shown previously in microbiological quality control of pharmaceutical products (Eissa, 2017). Data of SSI rates for each country was constructed using both I-MR and Laney-corrected attribute charts as could be illustrated

Table 4: Correlation Matrix showing two-tailed P and correlation coefficient (r) values at 95 % confidence interval (CI) for SSI rates from three nations monitored by WHO. (Generated using GraphPad Prism for Windows version 6.01)

Pearson correlation (rs) / P	KGZ	IRL	HUN
KGZ		-0.29	0.36
IRL	0.19		0.52
HUN	0.10	0.01	

in Fig. 3 to 5. In general, both (I) and Laney charts agree in both control limits and the first four alarm types. However, the variable type control chart offers more sensitivity by detecting other types of alarms, in addition to MR chart that measures the stability of the SSI percent or ratio variation with time. These findings are in agreement with what previously reported and noted in other works (Eissa, 2018a).

The use SPC to monitor the compliance to GXP has been conducted previously in pharmaceutical quality control study (Eissa and Abid, 2018). Similarly, in the present case, SPC tools show that improvements in SSI control measures in addition to its stabilization are strongly required. Implementation of standard protocols that should be enforced and monitored worldwide is strongly recommended in to limit the number of SSI per year and avoid any future excursions which may be life-threatening.

Table 5: Descriptive statistics of SSI yearly rates for the three countries under the study (Generated using GraphPad Prism for Windows version 6.01)

Column Statistics	KGZ	IRL	HUN
Mean	0.4486	0.8727	0.3809
Std. Deviation	0.1563	0.1702	0.1260
Std. Error of Mean	0.03332	0.03630	0.02686
D'Agostino & Pearson omnibus normality test			
K2	5.678	0.2101	0.8730
P value	0.0585	0.9003	0.6463
Passed normality test (alpha=0.05)?	Yes	Yes	Yes
P value summary	ns	ns	ns
Shapiro-Wilk normality test			
W	0.7992	0.9801	0.9398
P value	0.0005	0.9180	0.1956
Passed normality test (alpha=0.05)?	No	Yes	Yes
P value summary	***	ns	ns
KS normality test			
KS distance	0.3040	0.1217	0.1216
P value	< 0.0001	0.2000	0.2000
Passed normality test (alpha=0.05)?	No	Yes	Yes
P value summary	****	ns	ns
Coefficient of variation	34.83%	19.51%	33.08%
Geometric mean	0.4265	0.8565	0.3607
Skewness	1.184	0.1136	0.3516
Kurtosis	0.3355	-0.4740	-0.5807
Sum	9.870	19.20	8.380

ns: Not Significant KS: *Kolmogorov–Smirnov* Std.: *Standard*

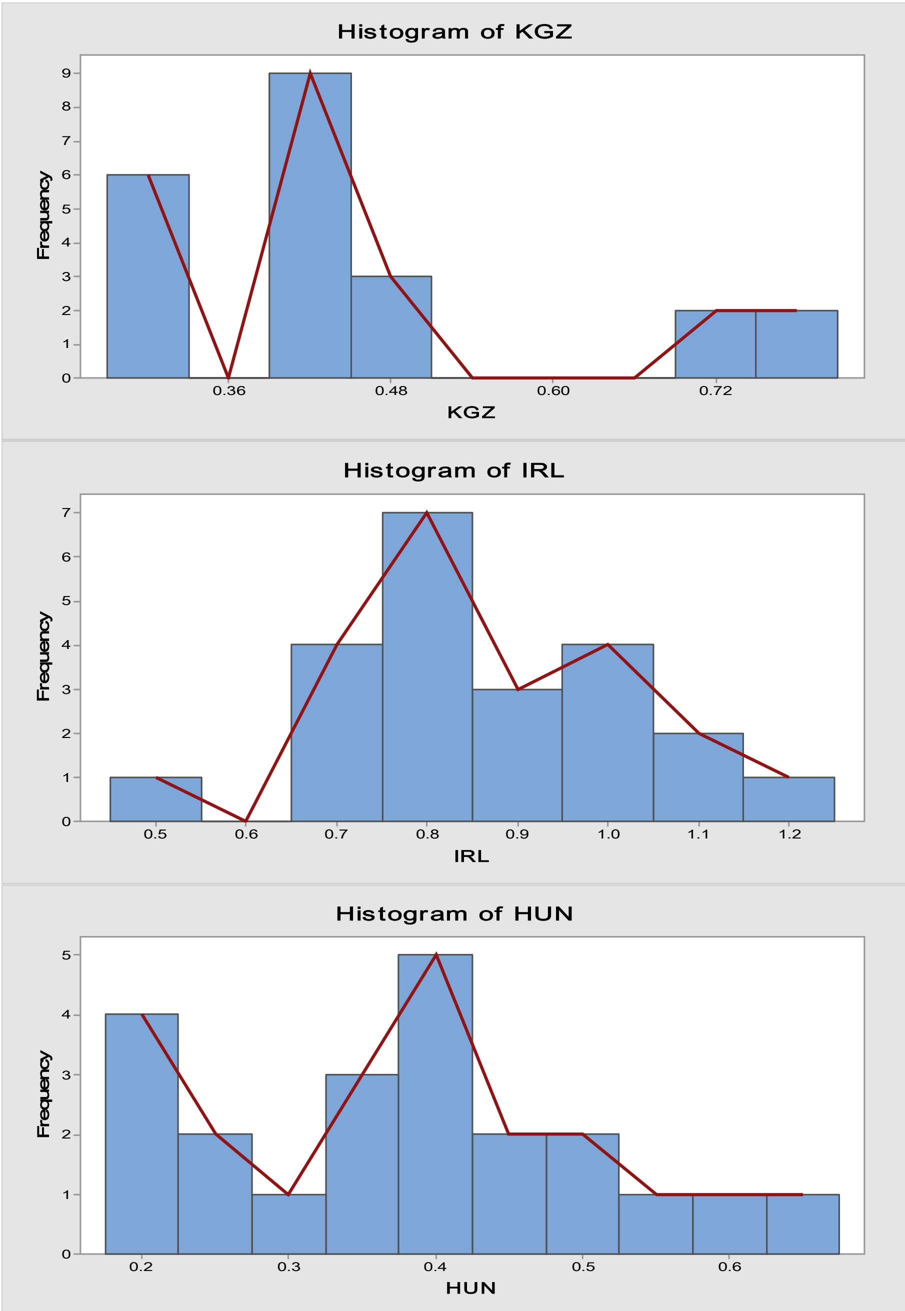


Fig. 1: Histograms of SSI yearly % of three nations recorded by WHO (Generated using Minitab® version 17.1.0)

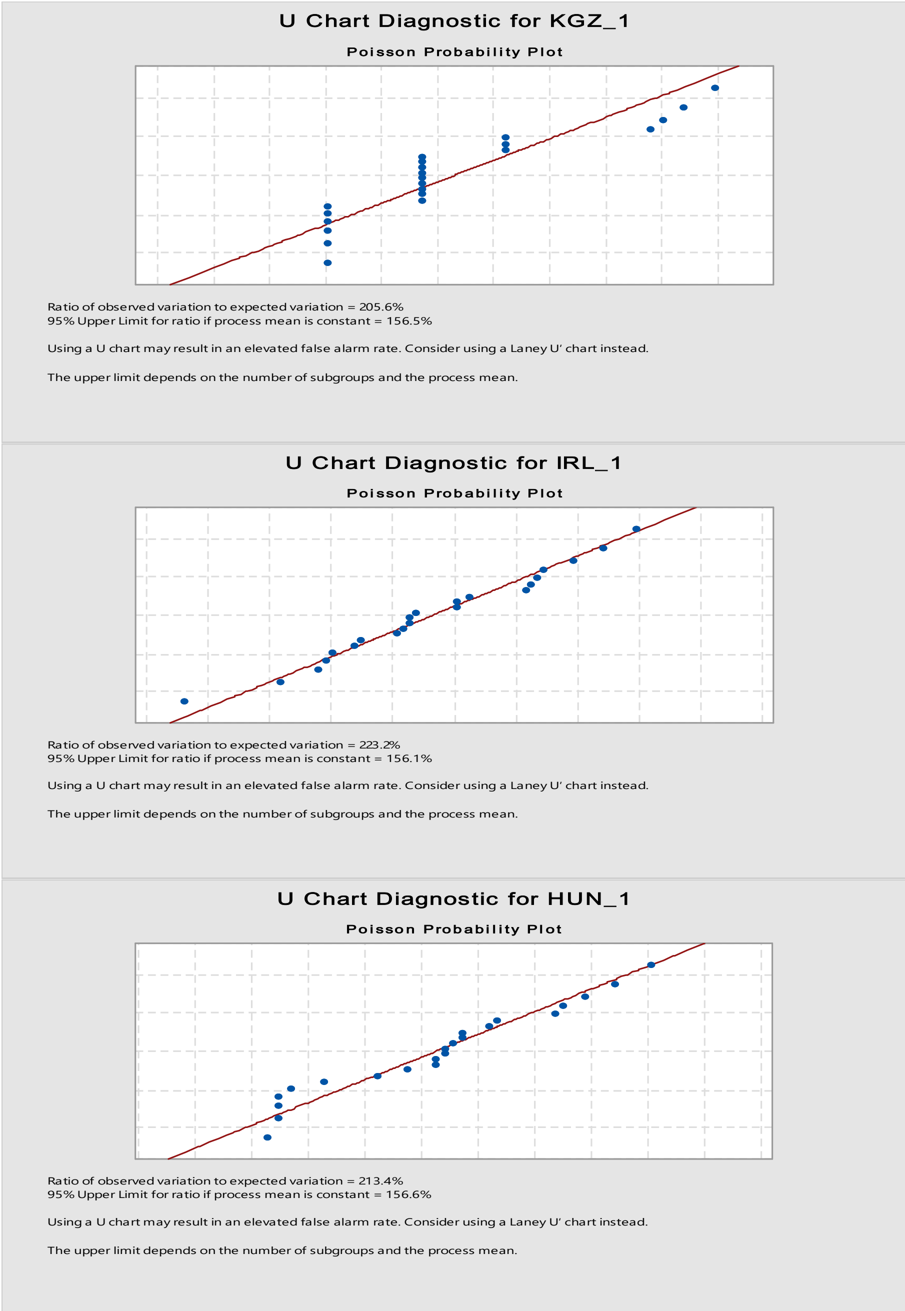


Fig. 2: Test for determination of suitability of ordinary attribute control charts for monitoring SSI rates from three nations (Generated using Minitab® version 17.1.0)

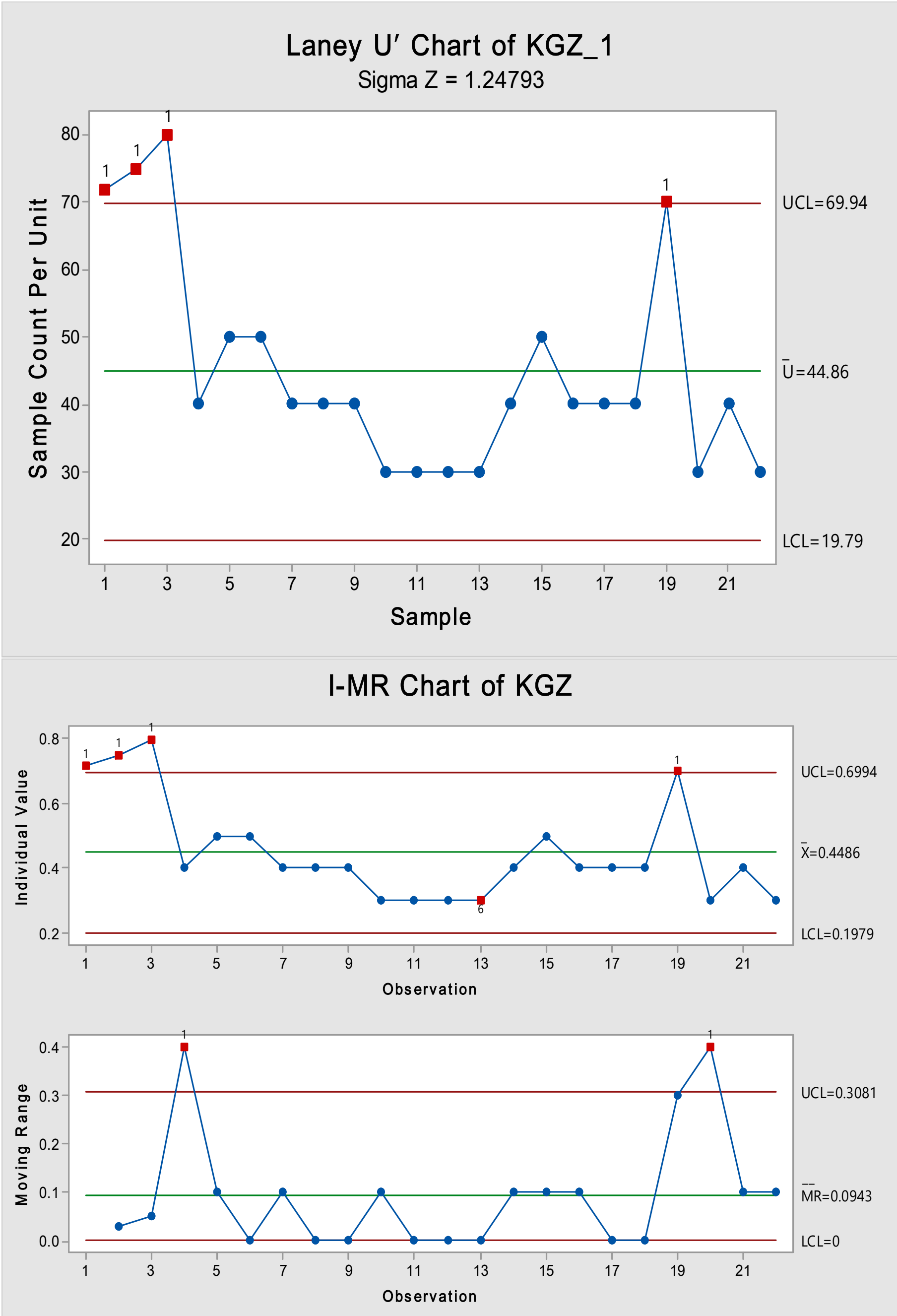


Fig. 3: Comparison between attribute and variable types of process-behaviour charts for monitoring of SSI rates in Kyrgyzstan (KGZ) (Generated using Minitab® version 17.1.0)

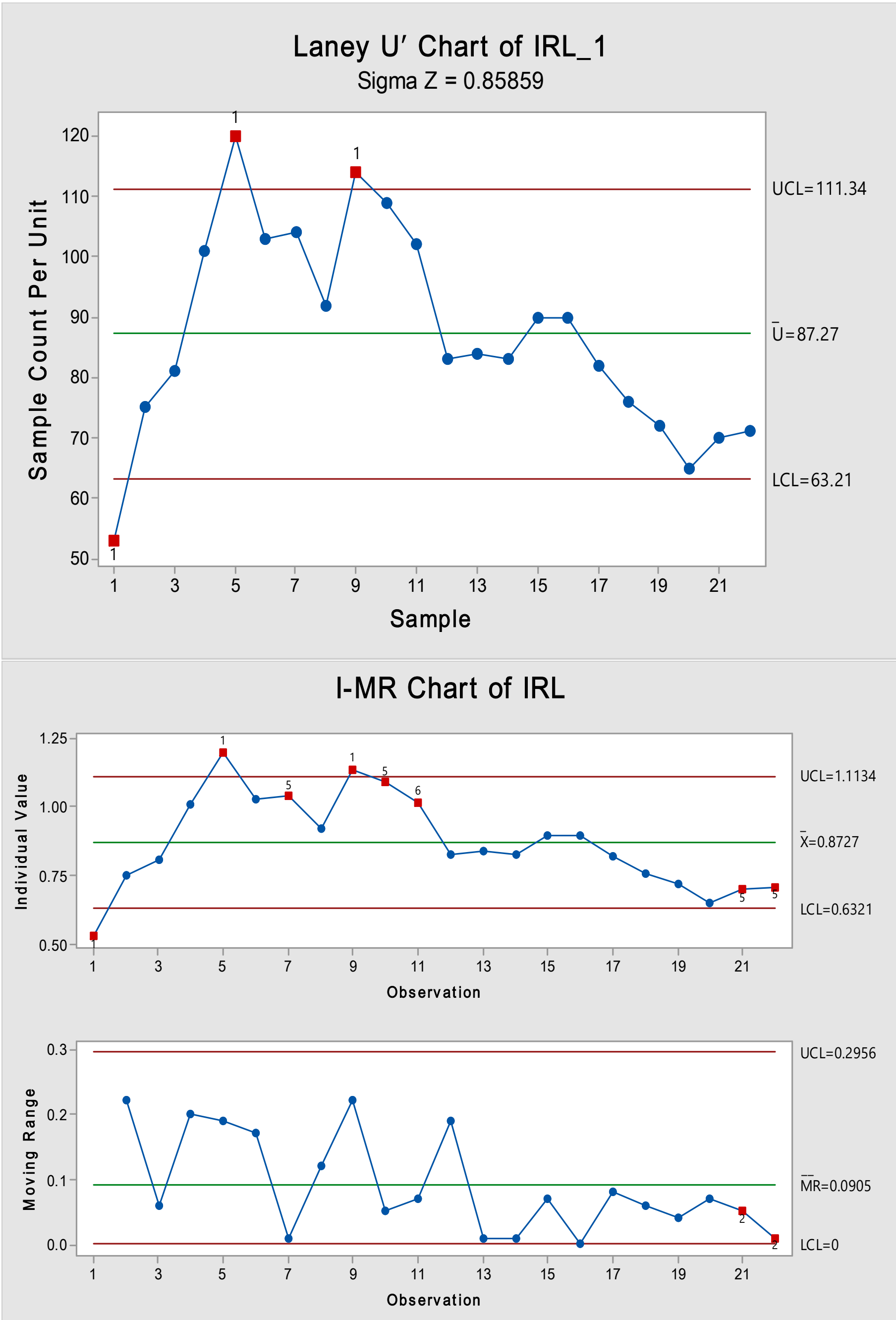


Fig. 4: Comparison between attribute and variable types of process-behaviour charts for monitoring of SSI rates in Ireland (IRL) (Generated using Minitab® version 17.1.0)

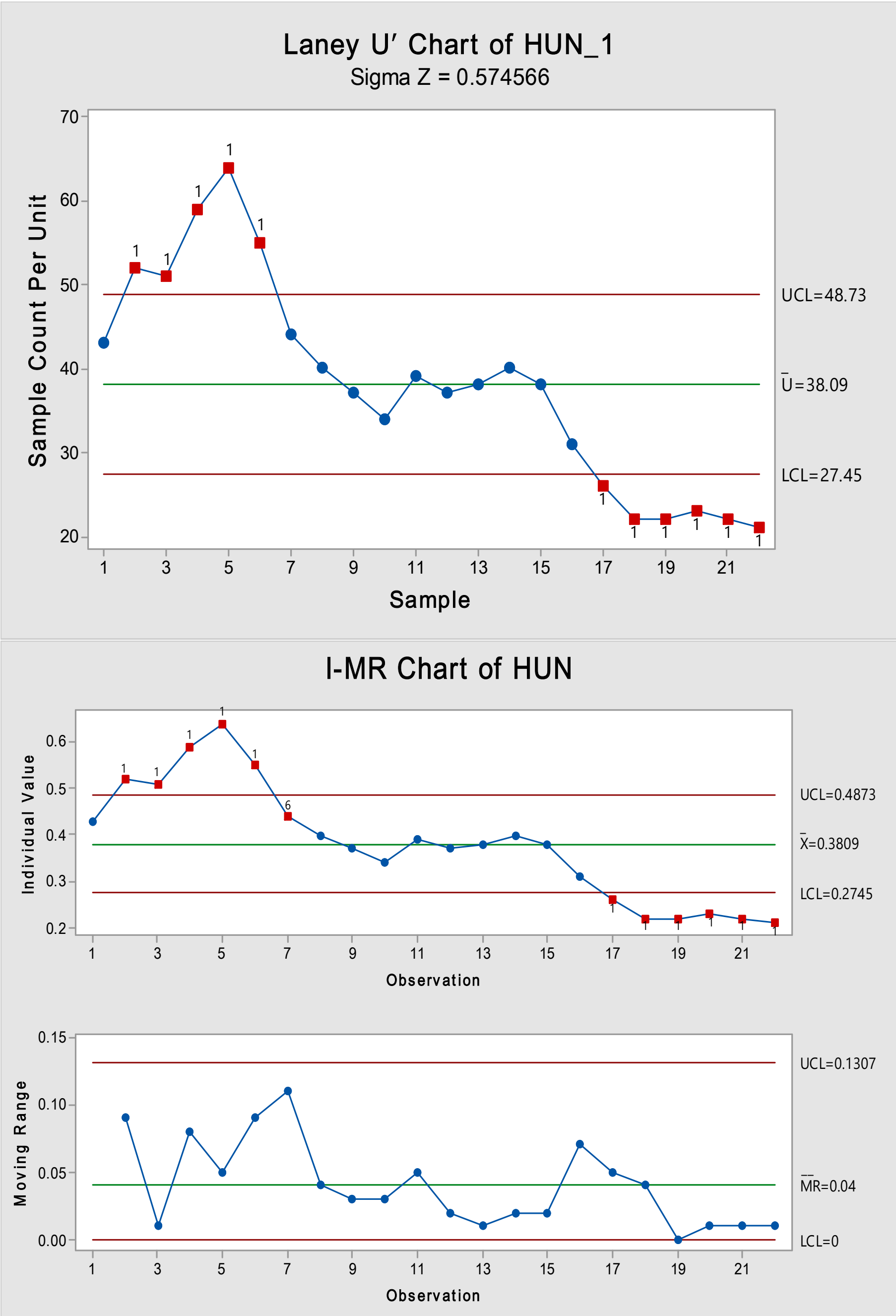


Fig. 5: Comparison between attribute and variable types of process-behaviour charts for monitoring of SSI rates in Hungary (HUN) (Generated using Minitab® version 17.1.0)

Conclusion

The current study showed that despite efforts made to lower the rates of SSI, there are intermittent excursions and unstable values of the inspection characteristic monitored with time due to the drifting of process means. Control charts should be updated regularly with data to provide a long-term estimation of the quality of measures taken to control infections and its robustness. In the presence of a certain degree of normality (as in the existing case), (I) and Laney U´ charts are similar in terms of control limits and some types of alarms but the variable type has an additional advantage of more sensitivity to other times of alarming signals, including those of the early process mean shift. In addition, MR chart provides another advantage in monitoring the stability of the variation of SSI percents from year to year.

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N/A

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