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Case of Preferential Selection of Attribute over Variable Control Charts in Trend Analysis of Microbiological Count in Water

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ABSTRACT

Monitoring the quality criteria in the healthcare industry and the pharmaceutical field specifically is a crucial mission activity to ensure the delivery of safe and effective treatment to patients with predictable and acceptable medicinal properties. One of the critical ingredients that are found in many activities is water. In the present study, the inspection characteristic trend was monitored by collecting results of the microbial count of Purified Water (PW) at two points in the water treatment station. The dataset was examined for pattern and distribution after processing and stratification and before conducting transformation using Microsoft Excel. Then, control charts were constructed using Statistical Process Control (SPC) software. The results showed that transformation improved data normalization for the Individual-Moving Range (I-MR) chart while the original pattern of the dataset was lost distorted. On the other hand, other advantages could be retained when using the Laney chart where no transformation was implemented on original raw data. The selection should be based on the nature of the process aim and condition.

INTRODUCTION

Consistency in the quality of the materials used in healthcare industry is crucial for delivering products with safe, predictable and effective properties to the final consumers (Mosadeghrad, 2014). These customers are usually health-defective and ill populations with a high risk of vulnerability to microbial infections. Water is one of the vital components in the industry that is involved in many activities (Eissa, 2016). Purified water is used in many non-sterile processes including pharmaceutical and biopharmaceutical manufacturing.

Water is highly dynamic in its inspection characteristics that may change and fluctuate rapidly under various conditions (Sardella et al., 2021). Thus, careful monitoring of its properties is of paramount importance. One of the critical quality items to be examined is the microbiological bioburden level (Eissa et al., 2022). Under these circumstances, the incorporation of the trending concept would be of great value over the reliance on the daily results only.

The use of the process behavior charts is an advantage in this situation as could be proved from earlier works that have involved quality management and improvement strategies following Six Sigma principles and rules (*Drinking Water and Health*, 1982). However, the appropriate selection of the trending chart is the dilemma that faces the interpreter, especially, if the primary database might be subjected to modifications, essentially the transformation due to a significant deviation in data distribution from the perquisite distribution (Eissa, 2015).

The crux of the present case is the presentation of two different point of view for analysis of dataset trends from non-normally distributed water samples results with pros and cons that could be drawn from the outcome of this investigation.

CASE STUDY

A small water plant for preparation of Purified Water (PW) from a municipal city source was monitored for quality characteristics, including total viable aerobic microbial count (TVAC) over about 16 months (70 weeks) on an average weekly basis. The number of accessible sampling ports was two: one after processing of water (denoted by PW) and the other at the Sanitization Port (denoted by SP) or specifically the Ultraviolet (UV) compartment. The sampling procedure, transfer and storage were conducted according to earlier research (Essam Eissa, 2018). Handling of samples, analysis, incubation and interpretation were performed using conventional microbiological techniques (Eissa, 2018a). Data were gathered and processed in Microsoft Excel then subjected to further processing using Statistical Process Control (SPC) software (Newton, 2014; Triola, 2014; Held, 2018; Levine et al., 2021).

Time-Series Investigation of the Microbiological Count in Water

Monitoring the mesophilic aerobic microbial count in water throughout the study period is illustrated in Figure 1 using a line graph and surface plot. The graphs showed three distinct levels of microbial count expressed as Colony Forming Unit (CFU)/100 mL. The baseline zone marked the close section to diminishing microbial count which is interrupted by the other two areas. The intermediate count zone showed microbial density between low and high bioburden. The last section demonstrated by few points but with spiking excursions towards the high microbiological population in water. The graph shows that the observed three ranges have visually different ranges from each other.

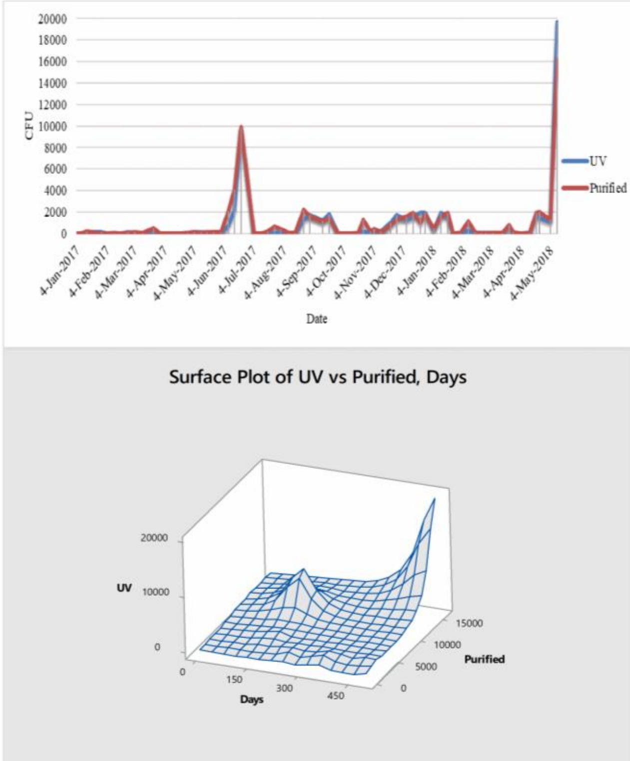

Figure 1. Time-series charts of the microbial contamination count of two monitoring points of the Purified Water plant as line graph (upper chart – generated using Microsoft Office 365) and surface plot (lower graph – generated using Minitab version 17.1.0).

Pareto Analysis of Bioburden Profile in Relation with Time

Pareto charts show the descending order of priority in terms of days based on the microbial density in water samples as could be seen from Figure 2 for the two use points' results. According to Pareto principle of 60/40 most populated water samples were found in April, May, June, August and January results. The wide variation range of the microbial count data distribution pinpoints the necessity of the statistical testing of the nature of the record-spreading pattern.

Examination of Dataset Distribution

The distribution and comparison of data before and after the logarithmic transformation study are demonstrated numerically in Table 1 and illustrated visually in Figures 3 and 4. The core finding from this section is that logarithmic transformation (to base ten) has significantly improved data normalization by reducing data scatter and spreading which is indicated by the absence of outliers after transformations. Accordingly, the use points' results had passed the Kolmogorov–Smirnov (KS) normality test, in addition to the noticeable improvement of skewness and kurtosis of the distribution curve. Also, the spreading between data points was appreciably reduced when variation parameters were reviewed.

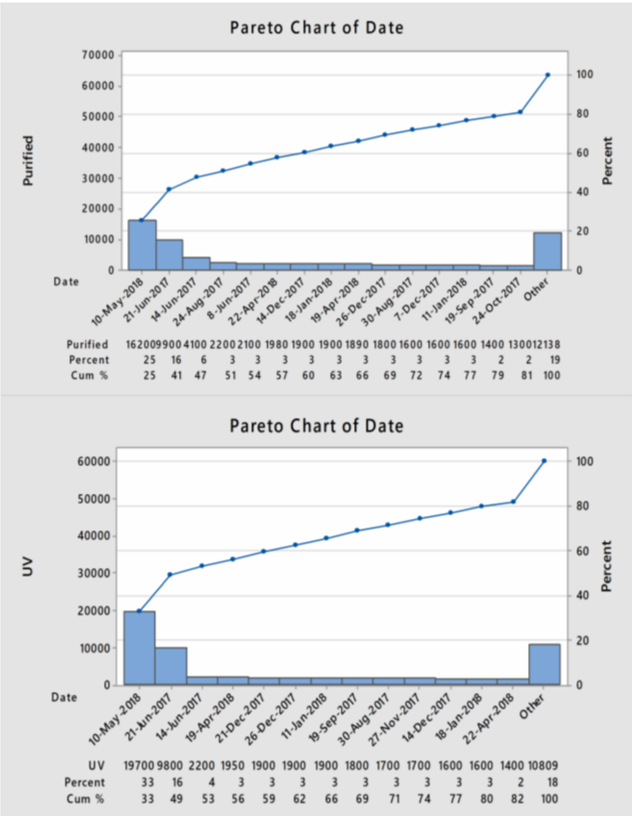

Figure 2. Pareto diagram showing days of the highest microbial count in descending order for two points of PW (generated using Minitab version 17.1.0)

Visual examination of the graphs (histograms, box plots and P-P graphs) would easily resolve the degree of improvement obtained from data logarithmic transformation in the reduction of scattering, removing excursions and normalization enhancement of the datasets for the two points-of-use. This could be viewed as a reasonable outcome for further statistical processing that might require normality assumption in the computation.

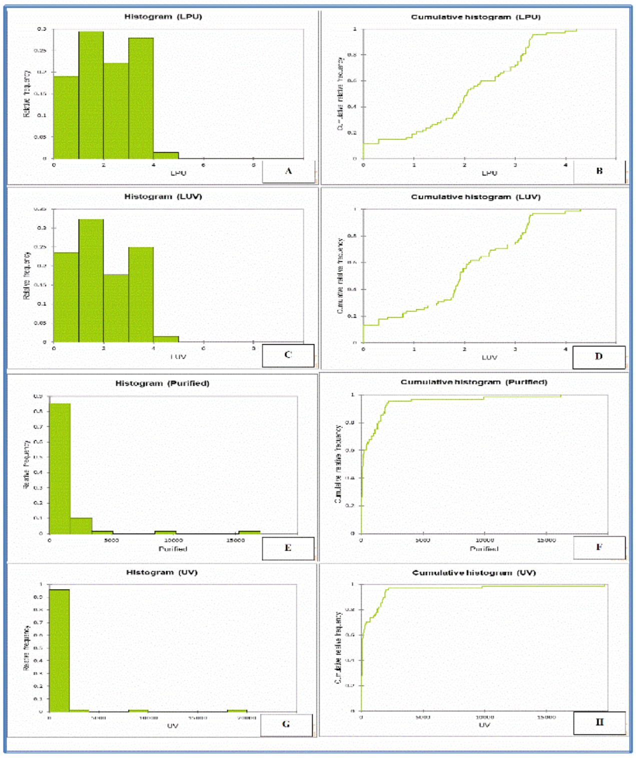

Figure 3. Comparison in distribution of data points between raw results (E, F, G, H) and logarithmically transformed microbial count (A, B, C, D) data [generated using XLSTAT add-in for Microsoft Excel]

Control Charts: Two Approaches Investigation

Two types of trending charts were used herein as an approach to monitor the process pattern and behavior. Figures 5 and 6 show attribute (For counting data, attribute control charts (most often integers, e.g., 4, 5, 6) and variable charts using variable controls for measurable data (most often decimals, e.g., 2.43) types of control charts, respectively. Red dots represent the alarming sample points that embrace assignable causes of variation which could be isolated from the common sources of natural variabilities in the inspection characteristics. The assignable differ from common causes variabilities in that they show special patterns between successive points rather than random variations that occur naturally in stable processes or inspection properties. These variations in turn embrace hidden factors that could lead to out-of-control situations with undesirable outcomes (Hubbard, 2003). Point "1" signals an alarm from abnormal extraneous factors. On the other hand, the number "2" pinpoints drift in the inspection characteristic means. However, in the Individual-Moving Range (I-MR) charts there are additional out-of-control identification numbers. For instance, "5" and "6" alarms are indicators samples for early warning of a possible process shift. Signal number "3" is a highlight for the improvement or deterioration of the trend of the microbial count. The assessment of the process center (I-chart) and the variation in the process (MR) demonstrated several special causes of variations in microbiological quality of water. It should be noted that transformation – as appeared in the figures – changed the shape of the original data pattern with extreme values retracted minimizing outliers in the dataset.

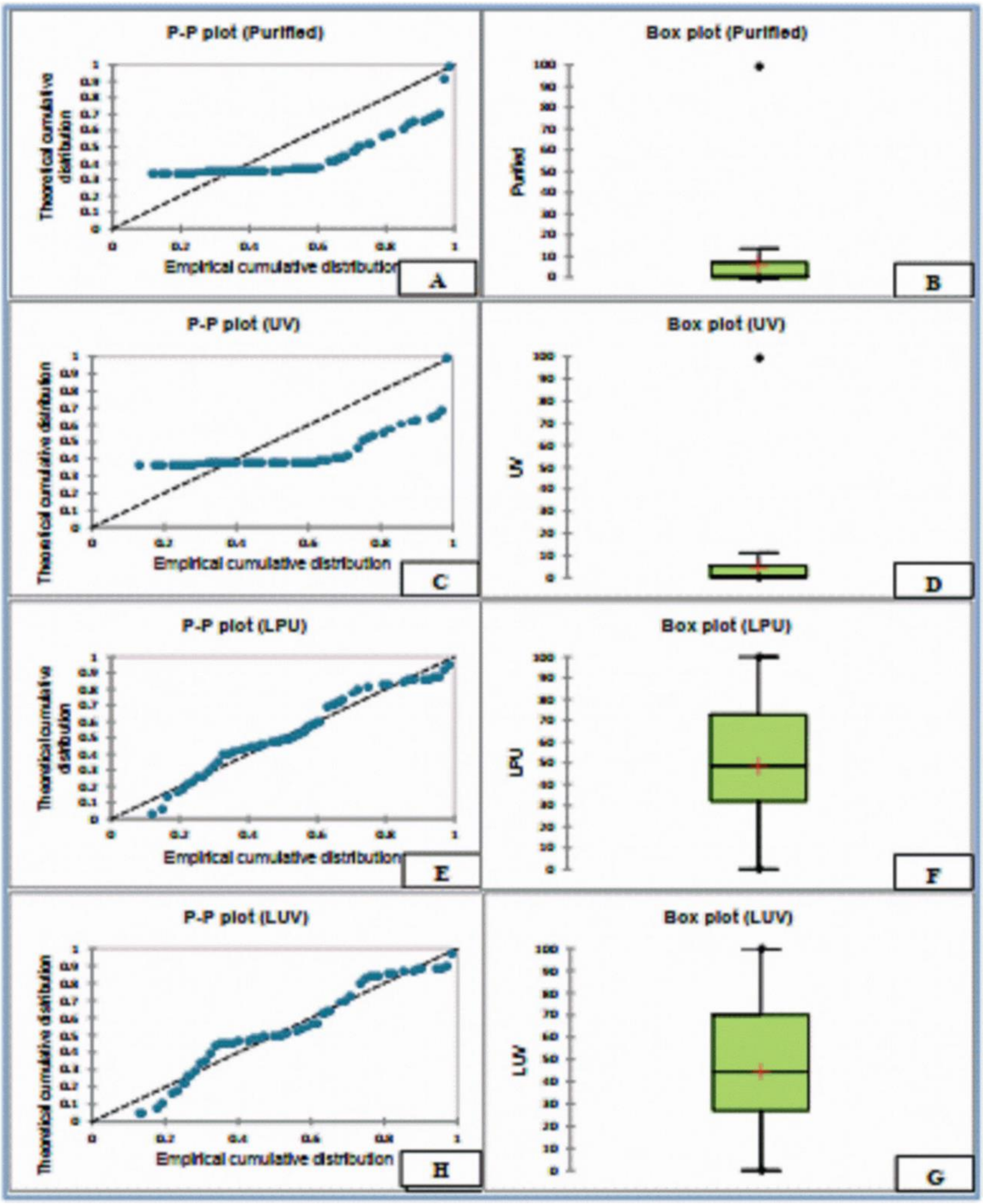

Figure 4. Probability–Probability plot (P value plot) (left column) and Boxplot (box-and-whisker) diagram (right column) showing raw (A, B, C and D) and transformed (E, F, G and H) data [generated using XLSTAT add-in for Microsoft Excel]

Table 1. Comparative descriptive statistics of microbial count results before and after transformation

Column Statistical Test[¥]	**SP**	**PW**	**LSP**	**LPW**
ROUT (Q = 1.000%)				
Outliers	18	3	0	0
Data Spreading Description				
25% Percentile[§]	11.25	20.50	1.082	1.332
Median[§]	80.50	110.5	1.911	2.047
75% Percentile[§]	1075	1250	3.032	3.096
Maximum[£]	19700	16200	4.294	4.210
Std. Deviation	2664	2337	1.151	1.127
Std. Error of Mean	323.1	283.4	0.1396	0.1366
Lower 99% CI of mean	24.02	183.1	1.535	1.687
Upper 99% CI of mean	1739	1688	2.276	2.412
Coefficient of variation	302.13%	249.80%	60.42%	54.96%
Skewness	5.983	5.170	-0.2312	-0.4060
Kurtosis	39.56	30.20	-0.8407	-0.6884
Kolmogorov–Smirnov (KS) normality test				
KS distance	0.3703	0.3445	0.1165	0.09928
P value	< 0.0001	< 0.0001	0.0228	0.0935
Passed normality test (α = 0.01)?	No	No	Yes	Yes
P value summary	****	****	*	ns
Sum	59959	63608	129.6	139.4

Note: ****: P ≤ 0.0001. *: P ≤ 0.05. ns: P > 0.05. ROUT: **Ro**bust regression and **Out**lier removal. SP: Sanitization Point. PW: Purified Water. L: Stands for Logarithmic transformation to the base ten for SP and PW. CI: Confidence Interval.

¥: Generated using GraphPad Prism version 6.01. Median: 50th percentile.

§: V = C × (d + 1)/100, where: *V* is percentile value, *C* is the target centile and *d* is the number of values in the dataset.
£: Minimum values of zeros are not shown in the table for no microbial count recovered.

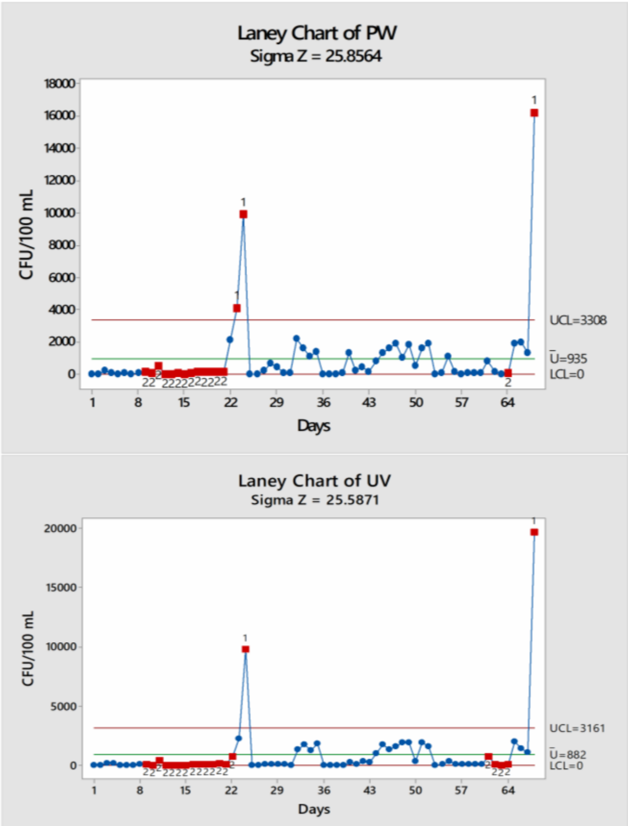

Figure 5. Laney attribute process-behavior charts of two PW point-of-uses in water treatment plant using raw dataset (generated using Minitab version 17.1.0)

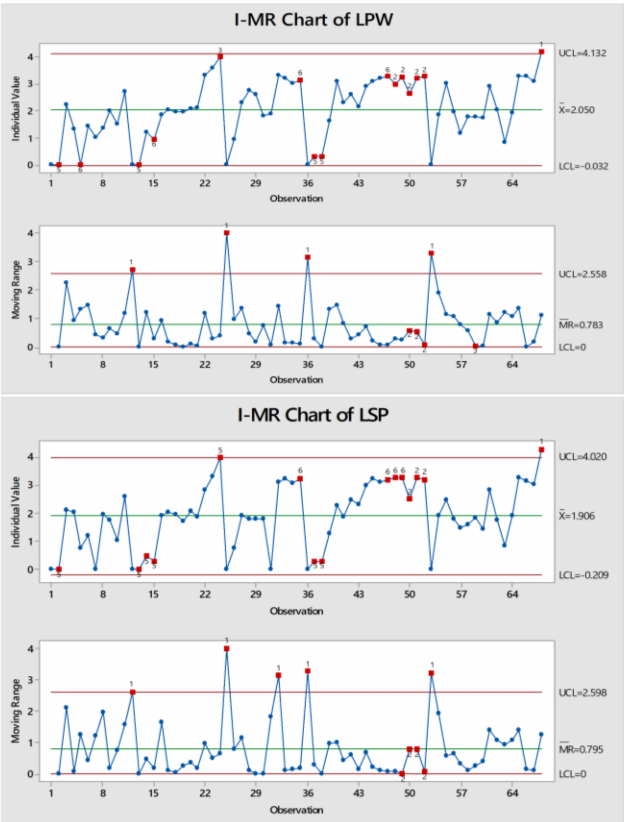

Figure 6. I-MR process-behavior charts with logarithmic transformation of two PW point-of-uses in water treatment plant generated using Minitab version 17.1.0)

DISCUSSION

Basically, control charts were designed to be used in the observation, control and monitoring of industrial objects such as product weight and dimensions (Hamed, 2017). However, process behavior charts gained popularity in other non-industrial applications (Wheeler, 2014). While setting exact parameter values in the trending charts might not be as critical for non-industrial properties as for the manufacturing ones by virtue of the processes or the inspection properties. Yet, they are still important to obtain quantitative outputs from the analyses that are reasonably informative and useful in the investigation of the inspection properties such as bioburden in water and to demonstrate acceptable and predictable levels of quality for ensuring acceptable consistency (Bhagwat, 2019). Controlling water quality for pharmaceutical purposes is at all costs a critical task that should not be underestimated and ignoring it would lead to devastating consequences (Bhagwat, 2019).

Recommendations have been postulated on the advantages of the variable over attribute trending charts as it could detect as twice as the known types of alarms in the charts that are used for discrete data type, in addition to the inclusion of another chart that accesses the process variability i.e., MR (Eissa, 2018b). This could be evident when comparing both types on the same set of data under the same conditions. In previous studies, comparison between variable and Laney-modified or corrected attribute charts has demonstrated agreement in the outcome interpretation between both types when conducted on the same dataset (Eissa, 2018b; Essam Eissa, 2018). However, transformation in the present case has changed the output derived from the I-MR chart when compared with the Laney chart projected on the original raw data.

Normality assumption for the use of variable control charts has been stated by various statisticians and experts (Khakifirooz et al., 2021). Despite the robustness of the I-MR chart has been demonstrated previously by some researchers, the Normalization procedure has been adopted in the present study to evaluate the pros and cons against the counterpart attribute chart through one of the well-known transformation paths (Keller, 2011; Elisson, 2017). This transformation tactic – for the original data - has been proved formerly to minimize data scattering and reduce outliers. Thus, Log_{10} [(CFU/100 mL) + 1] formula was used in the construction of data points in I-MR charts (Eissa, 2015; Smarter Solutions Inc., 2022). Number "1" in the equation is necessary to correct for zeros in the data record without distorting the data significantly.

On the same line, Laney's correction of the attribute chart was used for datasets that failed to show Poisson distribution assumptions of u or c charts. In this case, Laney modification was used to mitigate the risk of possible elevated alarm rates (Laney, 2002). This correction would be important to keep an eye on a process' defect rate and make any necessary adjustments for over- or under-dispersion in the present data. A conventional chart (for multiple defects per unit (D/U)) may display more points outside the control limits due to over- dispersion (Jones & Govindaraju, 2001). On the other side, a typical chart for this type of defect can display too few points outside of the control bounds due to under-dispersion. The Laney U' chart makes these adjustments of the control limits to avoid false warning signals.

A Laney-corrected chart's Sigma (σ) Z value shows how much the control limits are modified to account for over-dispersion or under-dispersion. In order to account for over-dispersion (as in the present case), the control limits on the Laney modified chart are wider than the control limits on a conventional D/U chart when the σ Z value is greater than the unity. An advantage of using this attribute chart over the I-MR chart is bypassing the transformation time and effort back and forth with less possibility of errors (Moon, 2020). Also, the merit of using the Laney chart in the present situation cannot be denied by being able to retain the same shape and profile of the original data without distortion so that abnormal points could be traced back to the original dataset chronologically.

The presence of additional types of alarm sensitivity did not seem to add much to the investigation of microbiological water quality in this work. However, the mean of the variable charts appeared much lower than that of the attribute ones for PW and SP points with values of about 113 and 81 CFU/100 mL (derived from the statistical software results) versus 935 and 882 CFU/ 100 mL, respectively (Skinner, 2018). Nevertheless, the Upper Control Limits (UCLs) for I-MR charts appeared much higher than that of Laney charts with values of 133552 and 10472 CFU/100 mL for PW and UV points which exceeds the Upper Specification Limit (USL) of 10000 CFU/100 mL. Accordingly, the Laney attribute chart was found more suitable for the initial preliminary examination of PW microbial quality with UCL values of 3308 and 3161 CFU/100 mL, respectively. Thus, the rate of detection of out-of-control points in the Laney charts was shown to be higher than in the corresponding I-MR graphs.

It should be noted that SL is a threshold value set by the formal authority or regulatory agent for an acceptable criterion of a certain subject while CL is the threshold computed from collected dataset arranged chronologically and would change based on the progressing variability of the monitored process or characteristic. When both limits are exceeded, it would be considered a critical chaotic issue that requires immediate extensive actions and investigation to prevent the occurrence of this incidence in the future. Water of poor quality will be produced if the process is under control, but the control limits are outside of the specification limits. The control limits will, in the ideal case, if centered inside of the specification limits with space to spare. The microbiological quality of water is stable and within the required process capacity if the CLs are within the SLs. It produces the best quality and has few inspection problems. The process also complies with consumer requirements. However, if one or more of the water samples showed results above CLs even if within SLs, then the process is unstable with out-of-control points detected then fast corrective and preventive actions (CAPA) are required to bring the process again within the stability window.

Laney charts could be easily correlated and interpreted along with time series plots and Pareto diagrams as could be seen from Figures 1 and 2 which facilitate the investigation of defect spot areas to correct the problem as a part of Corrective Action and Preventive Action (CAPA) plans (Motschman & Moore, 1999). This might not be quite evident in the transformed I-MR charts except when reviewed with the original series point-by-point to understand the pattern. Transformation minimized the scattering of the data points with the subsequent bringing on the extreme results closes together. Thus, low values appear higher and the high points become lower. Accordingly, the low critical points might appear exaggerated and the more crucial results would be underestimated. Experts in the quality field should understand when to use trending chart types by evaluating the confronted situation case by case depending on the nature of the inspection characteristics and the aim of the process. The authors suggest using the Laney attribute chart in the present case for simplicity and convenience, especially since the important aberrant patterns could be easily spotted in the time series charting.

Compliance with Ethical Standards

Authors' Contributions

MEE & DEE: Study conception and design

ER: Data collection

MEE, ER &DEE: Analysis and interpretation of results

MEE & DEE: Draft manuscript

All authors reviewed the results and approved the final version of the manuscript.

Conflict of Interest

The authors declare that there is no conflict of interest.

Ethical Approval

For this type of study, formal consent is not required.

Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article [and/or its supplementary materials].

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