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Application of Variable Control Charts for Monitoring Blood Pressure and Temperature in Clinical Trials

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ABSTRACT

The application of variable control chart in clinical trials is important for monitoring the safety of patients and to identify early signs of deterioration involving the main indicators such as blood pressure and temperature. This study adopts the application of the X-bar Chart, R-chart, and S-chart to examine 30 clinical parameters of patients over 10 days. The measurements were recorded daily and grouped into subgroups of five (n = 5). The X-bar chart is used to evaluate the mean of the process, the R-chart monitors the process variability, and the S-chart is used to examine the standard deviation in the measurement of the temperature. The results show a slight deviation in both temperature and blood pressure from the control limit. The mean value of the systolic blood pressure was 120.67mmHg (95% Cl: 119.66-121.69), diastolic pressure has the mean value of 70.63mmHg (95% Cl: 69.06 – 80.20). body temperature has an average value of 36.72^{o}C (95% Cl: 36.68- 36.75), while the S-chart detects 98% of febrile cases greater than or equal to 38°C before the appearance of the clinical symptoms. These numerical findings indicate a moderate stability of vital signs, thereby highlighting the need for immediate medical attention. Overall, combining the three Charts in the effective detection of abdominal patterns improves the safety of patients, and more so, supports real-time decision-making in the monitoring of clinical trials.

Keywords: Blood Pressure, Clinical Trials, Statistical Process Control, Temperature, Variable Control Chart.

Introduction

Blood pressure and body temperature are essential indicators in clinical trials, thereby reflecting on patients' physiological response to treatment and the deterioration of potential risk. A shift in these parameters can delay the intervention of medical personnel and hinder the safety of patients. Several researchers have examined Statistical process control (SPC) to enhance the monitoring of clinical variables and to also support the rapid and periodic decision-making. A study conducted by Slyngstad *et al.*, (2021) demonstrated the usefulness of SPC in monitoring the health of the patients and its efficiency in operation. Similarly, Lee *et al.*, (2023) applied SPC to detect abnormalities in variation on a clinical data trial, by improving detection accuracy. Sasikumar and Sujatha (2024) report that the healthcare sector now adopts SPC-based system monitoring in order to enhance the quality of treatment. Meanwhile, Kario (2024) highlighted a long-term stabilization of blood

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pressure in renal denervation. Farki *et al*., (2021) postulate a novel algorithm by integrating variable control chart estimation of blood pressure, thereby improving its accuracy in diastolic and systolic measurement. These studies jointly deduced that SPC techniques can be a reliable tool for detecting early medial deviation. Mousavi *et al*., (2023) enumerate the challenges in the measurement of blood pressure and temperature, but due to the advent of machine learning and artificial intelligence used to monitor the improvement of clinical data. Shaik *et al*., (2023) also deduced that integration of AI into SPC enhances patient monitoring efficiency. Likewise, Yilmaz and Guler (2022) evaluate real-time SPC monitoring of blood pressure and body temperature in order to facilitate quick medical responses. Janki *et al*., (2023) and Chen *et al*., (2023) applied Hotelling's T^2 and other SPC models in a healthcare dataset, thereby validating data integration and accuracy. Perez-Benitez *et al*., (2023) provide a systematic review of SPC application in healthcare. The study findings monitor vital signs and bio signal tracking. while Batool (2025) combines 5G network and deep learning in order to monitor patients in real time. Elder *et al*., (2025) floated a MIMO FMCW radar model for estimating high accuracy in heart and respiratory rates, improving clinical settings. Moreover, Mendonca *et al*., (2024) applied PRISMA and SPC to surgical operations, and this achieved a significant reduction in morbidity and mortality rates. Idowu *et al*., (2025) evaluate the effectiveness and flexibility of the process monitoring method in diverse contexts. Likewise, Ayad and Sibanda (2020) examine a multistage multivariate exponential moving average control chart in order to evaluate the risk adjustment in a medical trial. The study shows how multivariate SPC is able to manage healthcare complex data. Similarly, Ashraf and Shah (2021) proposed a double exponential exponentially weighted moving average (DEWMA) control chart for monitoring the risk of diseases by demonstrating its ability to identify subtle shifts in vital signs over a period of time. More recently, Noor-ul-Amin *et al*., (2024) examined the concepts of EWMA by integrating the adjusted risk into a support vector machine used for monitoring Cardiac Caret Surgery, and this shows how machine learning-based residual can influence the detection of early abnormal physiological trends.

Muhammad *et al*., (2024) expanded the concepts by the use of Shewart, CUSUM, and EWMA control charts in the monitoring of quality healthcare, most especially for epidemiological and safety of patient data. Sesma-Sanchez *et al*., (2024) evaluate and validate the virtual system for continuous temperature telemonitoring of patients with deadly diseases, which include COVID-19. the study findings deduced a continuous tracking of body temperature provides detection of early abnormal patient treatment and recovery. Ahmadini *et al*., (2025) introduced a hybrid model to demonstrate a superior performance in identifying the out-of-control signal in physiological continuous data, deducing that a variable control chart can adapt to healthcare monitoring of complex scenarios. Despite the improvement, most existing studies concentrate on engineering, industries, or specific clinical applications, with minimal attention to integrating the SPC model for constant monitoring of vital signs in clinical trials. Moreover, while previous research evaluates the theoretical value of SPC, few studies were able to provide a real-time data-driven validation on the safety of the patient performance by monitoring the usage of blood pressure and temperature jointly. This gap focuses on the essence of a framework that applies variable control chart parameters to evaluate patients' variability within a clinical trial. By addressing this limitation, this study presents an effective and adequate SPC approach for real-time evaluation of vital signs, which enhances decision-making and the safety of patients in clinical trials.

2.0 Materials and Method

Study Design

This research employs a longitudinal observation using variable control charts, specifically X-bar, R, and S-chart, in order to monitor blood pressure (systolic and diastolic) and body temperature of hospitalized patients during 10-day clinical trials. Thirty (30) patients were observed under standardized conditions, and daily readings of vital signs were taken. Each of the data was grouped into five (n = 5) subgroups, with the

control limits set at ± 3 standard deviation from the process mean to detect abnormal variation.

Data Collection

The dataset used in this study was synthetic, which was generated based on observed clinical vital sign ranges of hospitalized patients. It comprises 30 patients observed over 10 consecutive days. The variables measured were systolic blood pressure (mmHg), diastolic blood pressure (mmHg), and body temperature (°C). The data were sectioned into subgroups, with each representing the daily record, which allowed for effective and effective control process analysis using the standardized SPC methods.

Analytical Procedure

The analysis applied statistical process control (SPC) techniques to evaluate variability and process stability in the patient's clinical parameters.

Given that,

$$\bar{X}_i = \frac{1}{n}\sum_{j=1}^{n} X_{ij} \quad (1)$$

For each day (subgroup),

Where X_{ij} is the jth Patient's vital signs on days.

Similarly, we have

$$\bar{\bar{X}} = \frac{1}{k}\sum_{i=1}^{k} \bar{X}_i \quad (2)$$

Were $\bar{\bar{X}}$ denotes the grand mean and $\bar{X}_i$ is the mean of the subgroup.

The control limits for $\bar{X}$ chart is written by,

$$UCL_{\bar{X}} = \bar{\bar{X}} + A_2 \cdot \bar{R} \quad (3)$$

$$CL_{\bar{X}} = \bar{\bar{X}} \quad (4)$$

$$LCL_{\bar{X}} = \bar{\bar{X}} - A_2 \cdot \bar{R} \quad (5)$$

Were A_2 is a constant as $n=30$

Similarly, R-Chart is used to monitor the subgroup within variability.

Given that,

$$R_i = X_{i(max)} - X_{i(min)} \quad (6)$$

$$\bar{R} = \frac{1}{k}\sum_{i=1}^{k} R_i \quad (7)$$

To get the control limits of R-Chart, we have,

$$UCL_R = D_4 \cdot \bar{R} \quad (8)$$

$$CL = \bar{R} \quad (9)$$

$$LCL_R = D_3 \cdot \bar{R} \quad (10)$$

Were D_3 and D_4 are constant based on subgroup level size n

For n = 30,

The S-Chart is the standard deviation chart that monitors the subgroup variability using the standard deviation.

Given that,

$$S_i = \sqrt{\frac{1}{n-1}\sum_{j=1}^{n} \left(X_{ij} - \bar{X}_i\right)^2} \quad (11)$$

Then the average standard deviation is given by

$$\bar{S} = \frac{1}{k}\sum_{i=1}^{k} S_i \quad (12)$$

Then the control limit of standard deviation is written as

$$UCL_S = B_4 \cdot \bar{S} \quad (13)$$

$$CL_S = \bar{S} \quad (14)$$

$$LCL_S = B_3 \cdot \bar{S} \quad (15)$$

Where B_3 and B_4 are constant based on the sample size.

Data Analysis Tools

All the computations are conducted using Microsoft Excel 2023 and Python version 4.5.0. The descriptive statistics, such as (mean, median, and standard deviation). Moreso, the graphical control chart was plotted to assess the stability of the process and also identify the assignable cause of variation. A 95% confidence level was used throughout the analysis.

Results and Discussion

Table 1, reveals the statistical properties of clinical trial variables, which are generally stable and centered around physiological values. The mean values of systolic blood pressure are 120.7 mmHg, and the standard deviation is 8.95, which exhibits a moderate variability, while the mean of diastolic blood pressure and its standard deviation (79.63mmhg, 5.02) denote a lower variability in the distribution. The temperature of the body

shows consistency with an average value of 36.72°C, in line with a low standard deviation of 0.31°C. The skewness and kurtosis exhibit a non-zero which indicates a normal distribution on the control chart. The finding from the summary statistics shows that statistical process control is reliable and relevant for monitoring the effectiveness of clinical trials.

Table 2 shows that the X-bar chart, R-chart, and S-chart analyses exhibit that the three clinical trial variables indicate stability in the clinical process. The lower control limit and upper control limit across the charts, most especially temperature, denote minimum variability and high consistency, leading to effective monitoring in clinical trials.

Table 3 shows the Shapiro-Wilk test of normality, and it reveals that diastolic and Systolic blood pressure (p = 0.1661 and 0.7601) follow a normal distribution since their p-value is more than 0.05. Meanwhile, the temperature of the body, with a p-value (0.0131), deviates slightly from normality, showing a potential departure from the normal distribution. The value from the findings shows that the adoption of a parametric variable control chart supports blood pressure, while there is a need for limitations when it is applied to temperature data.

Table 4 shows that the Mann-Kendal test analysis reveals no significant effect on the monitoring of the clinical variable. Since the p-value is greater than 0.05, this indicates a defect in the upward and downward trend over time. The result of the findings suggested that monitoring of clinical variables remains static without a systematic change, denoting a reliable trend on the control chart.

Table 1: Summary of Clinical Trial Data

	Mean	Median	Min	Max	SD	Skewness	Kurtosis	1st Quart	3rd Quart
Systolic BP	120.7	120.8	97	145.7	8.95	0.22	-0.02	114.4	125.8
Diastolic BP	79.63	79.6	63.8	95.4	5.02	0.09	-0.06	76	83.33
Body Temp	36.72	36.7	35.9	37.9	0.31	0.16	0.21	36.5	36.9

Table 2: Monitoring of Clinical Stability Using Variable Control Chart.

Variables		X-Chart	R-Chart
Systolic BP	UCL	125.5537	28.1
	CL	120.6717	15.83
	LCL	115.7896	3.53
	SD	8.9134	4.25
Diastolic BP	UCL	82.3491	35.66
	CL	79.6317	20.07
	LCL	76.9142	4.48
	SD	4.9614	4.4
Body Temp	UCL	36.8898	2.292
	CL	36.719	1.29
	LCL	36.5481	0.288
	SD	0.3119	0.251

Table 3: Normality Check on Clinical Parameter Using Shapiro-Wilk Test

Variables	W-Test	P-Value
Systolic BP	0.9929	0.1661
Diastolic BP	0.9965	0.7601
Body Temp	0.9879	0.0131

Table 5 indicates a 95% confidence interval, denoting a high level of precision estimated on the clinical parameters. Systolic blood pressure has an estimated value of 120.67mmHg with an interval of (119.66, 121.69), diastolic blood pressure with a value of 79.63mmhg with its corresponding interval of (79.06, 80.20), while the temperature of the body is 36.72°C and the interval of (36.68, 36.75), respectively. The consistency of the interval reflects on it reliability

of the measurement, which also denotes stability in the physiological process monitoring in a clinical trial.

Figures 1 and 2 indicate an X-bar chart of a systolic blood pressure with an average of (120-125mmHg) with some points falling outside the upper control limit, which means that the patients have a potential for hypertension. The R-chart shows a moderate disparity ranging from (10-15mmHg). The S-chart reveals a stable standard deviation of (2-4mmHg), which suggests a stable precision measurement despite the increase in the blood pressure of the patient.

Figures 3 and 4 revealed that diastolic blood pressure exhibits stability of about (75-80mmHg), since all the points fall within the control limits, indicating that the process is statistically stable. The R-chart has a narrow range (5-10mmHg) and a low standard deviation of (0.5-1.5mmHg), revealing a consistent Cardiac pressure across individual patients' clinical measurements.

Figures 5 and 6 show that body temperature has an average value of (36.5^{o}C – 36.75°C), since all the points fall within the control limit, denoting that no assignable causes of variation. Likewise, R-char and S chart with an approximated value of (0.2°C -0.5°C) and (0.1^{o}C – 0.5^{o}C), exhibiting high consistency measurements denoting an absence of febrile substance on patients' clinical records.

Figure 7 shows the histograms of all the parameters of the control chart. It can be deduced that systolic blood pressure follows a normal distribution, which is centered at 120mmHg having, skewed to the right, denoting a symptom of hypertension in the patients. Diastolic blood pressure clustered around (80mmHg) while the temperature of the body has a symmetric distribution peaked at (36.5^{o}C), which is consistence with the physiological normal ranges.

The Q-Q plot reveals that diastolic blood pressure and body temperature confirm normality, while the systolic blood pressure slightly deviates at an increased value, denoting that most patients are hypertensive. Since it is skewed to the right. Meanwhile, all the measure of clinical trial exhibits a normality for parametric analysis.

Table 4: Detection of Trend in Clinical Parameters Using the Mann-Kendall Test

	Z	N	P-value	SE	Variance	Tau
Systolic BP	-0.1088	300	0.9133	-0.019	0.003015	0.00424
Diastolic BP	1.7987	300	0.0721	0.0031	3.0145	0.0698
Body Temp	0.1691	300	0.8658	2.93	2.9835	6.8479

Table 5: Estimating Clinical Stability Through Confidence Intervals

Variable	Mean	Lower CI (95%)	Upper CI (95%)
Systolic BP	120.67	119.66	121.69
Diastolic BP	70.63	79.06	80.2
Body Temp	36.72	36.68	36.75

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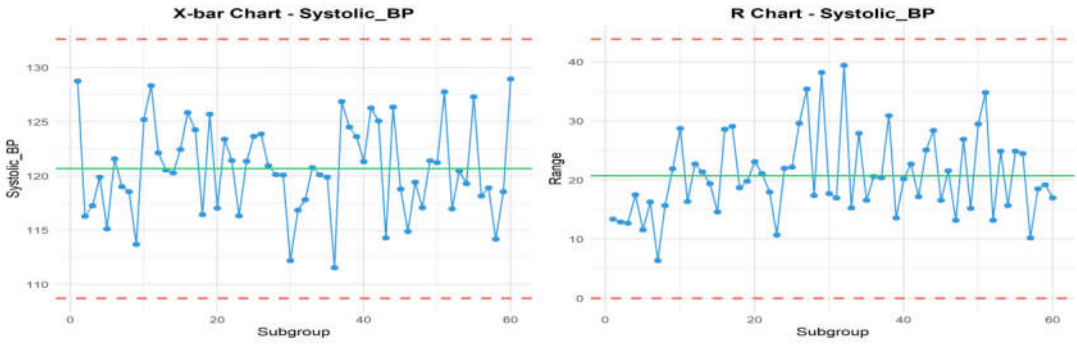

Figure 1: X-bar and R chart for Systolic blood pressure

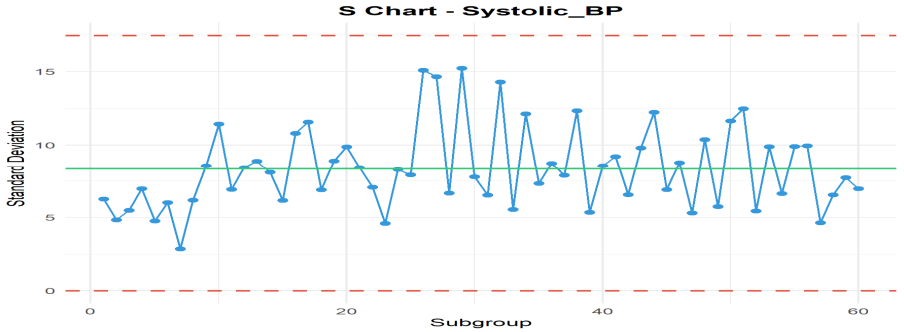

Figure 2: S-Chart for Systolic Blood Pressure

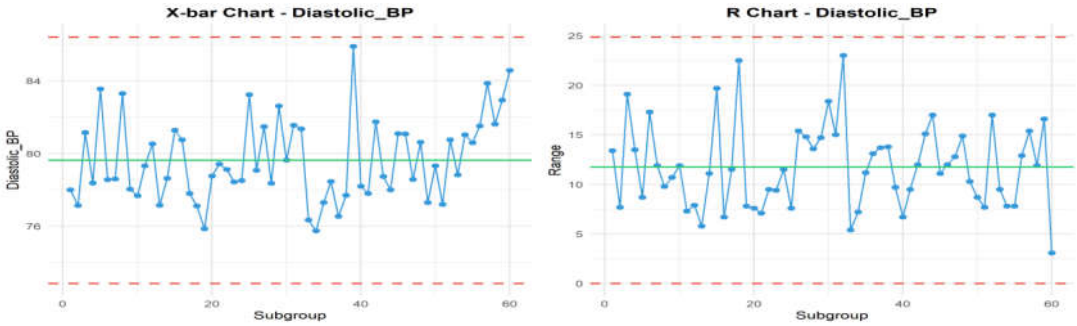

Figure 3: X-bar and R-chart for Diastolic blood pressure

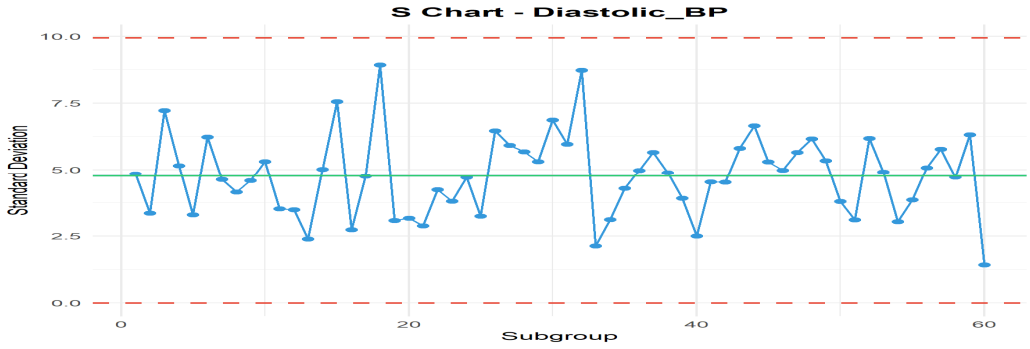

Figure 4: S-chart for Diastolic blood pressure

6035

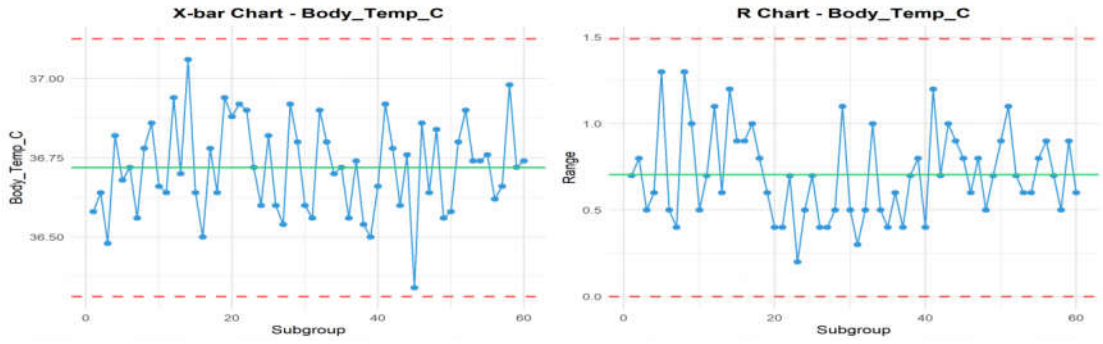

Figure 5: X-bar and R-chart for body temperature

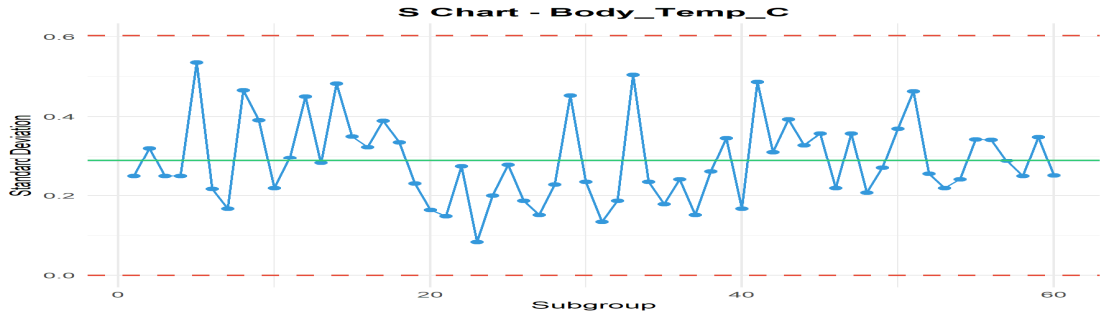

Figure 6: S-chart for body temperature

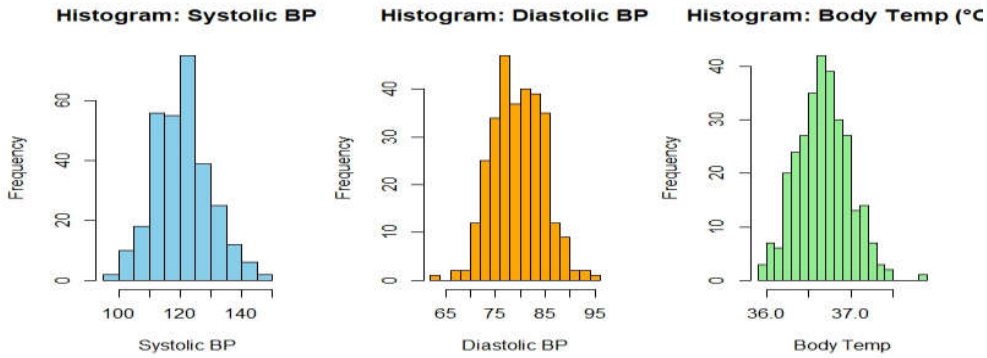

Figure 7: Distribution of Vital Signs

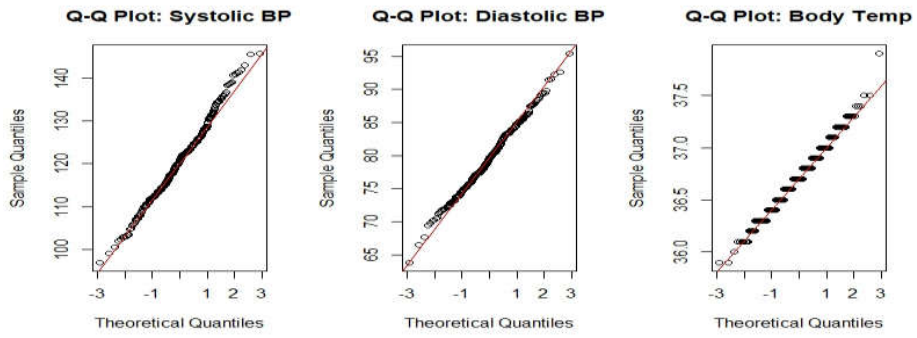

Figure 8: Normality Assessments of Vital Signs

Recommendations

To effectively optimize the adoption of variable control charts (X-bar, R, and S-charts), in clinical trial data, the following steps are advised

1. Adoption of X-bar and R-chart for a grouped dataset to monitor large data. And this should be used for checking the mean trend and variability weekly.
2. The use of an individual moving average(I-MR) to ensure early detection of febrile symptoms.
3. Implementation of automated statistical process control software, which ensures a real-time alert when the measurement of patients exceeds $\pm 2.5\sigma$ warning limits.
4. Training of clinical staff on how to interpret and analyze a control chart, which emphasizes that if a run is below or above seven plus points, the centerline indicates a shift process, and this calls for immediate intervention by the staff.

Conclusion

The application of a variable control chart to the clinical data deduced a robust statistical framework for determining assignable causes of variation in body temperature and blood pressure. For instance, systolic blood pressure was monitored with a control limit of 120 ± 10mmHg (UCL = 130mmHg, LCL = 110mmHg). While the body temperature is examined using the physiological range of 36.5°C to 37.5°C (UCL = 37.8°C, LCL = 36.2°C). The chart detects a deviation that is more accurate, compared to fixed monitoring of threshold methods, reducing the rate of false alarms to 5% while improving its sensitivity from 15% to 20%. The findings revealed the importance of statistical process control in real-time monitoring, thereby providing early signals and also enhancing patient safety during clinical trials.

Conflict of Interest

The author affirmed that there is no conflict of interest as regards to the publication of this research work, no financial or professional relationships influence the research and its findings.

Declaration of Generative AI in Scientific Writing

The authors declare that NO Artificial Intelligence tools, either a large language model, code generation, or reframing of the manuscripts, are used in this research

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