STATISTICAL PROCESS CONTROL CHARTS: A QUICK GUIDE FOR CLINICIANS

Control charts are powerful tools for monitoring process stability and variability. Different types of control charts are suited for different types of data and scenarios. This document outlines the rules for selecting the appropriate control chart.

DEFINITIONS

This section provides definitions of concepts used throughout the document.

- **Sample size** refers to the number of individual measurements or observations collected in one group/subgroup/batch during a specific time period or under specific conditions.
    - **Example:** If 200 babies were discharged from hospital in a month, the sample size is 200 for that month.
- **Subgroup** refers to a small, representative sample of measurements or observations within the larger sample, which are collected under similar conditions.
    - **Example:** If 100 babies discharged from the hospital were male and another 100 were female, each subgroup consists of 100 babies.

1.0 STEPS TO CHOOSE THE CONTROL CHART TYPE

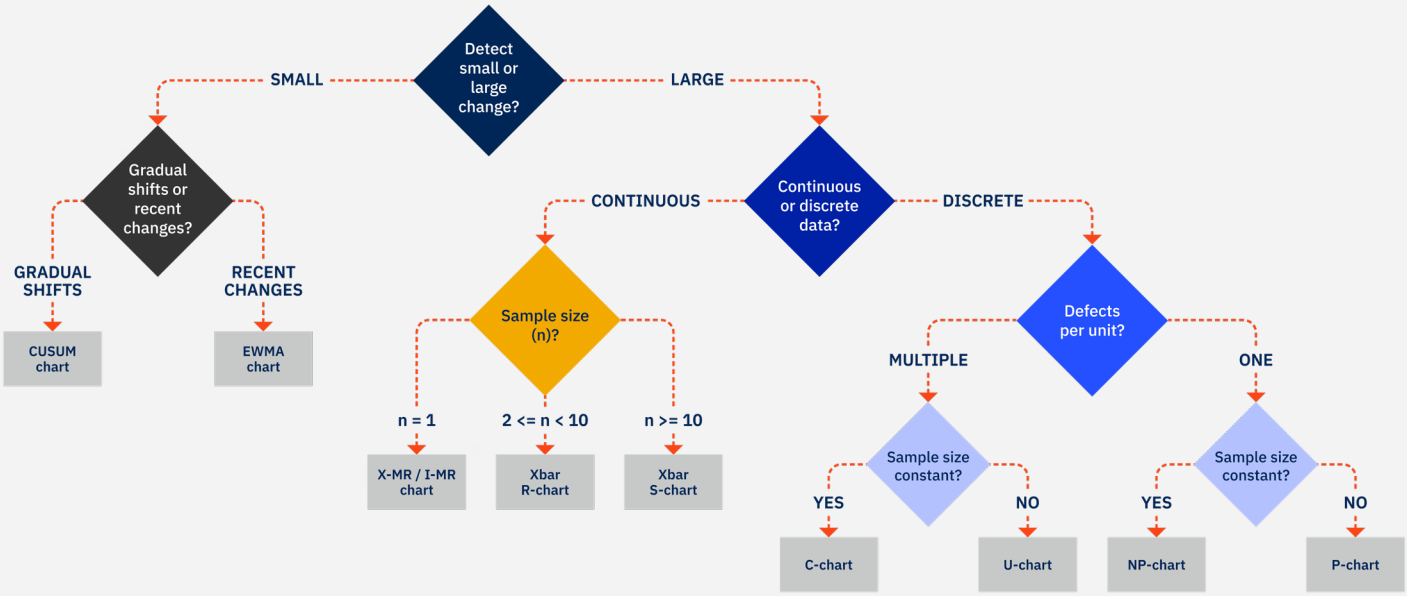


Figure 1. Control Chart Selection

Figure 1 shows basic steps on how to select the right control chart. More details about each step and additional requirements are provided below.

Step 1: Decide whether large or small changes need to be detected

- **Large change** is considered a deviation of 1.5 or more standard deviations from the mean.
- **Small change** is considered a deviation of less than 1.5 standard deviations from the mean.

1.1 DETECTING SMALL CHANGES

Step 2: Determine data distribution

For all control charts in this group, it is assumed that data follows normal distribution even though it is not strictly required. Data that significantly deviates from normal distribution might benefit from a transformation to normal distribution (e.g., logarithmic transformation) to ensure good performance of the control chart.

Step 3: Determine whether the interest is in gradual shifts or recent changes

1.1.1 Gradual shifts

Chart: Cumulative sum (CUSUM) control chart

Assumption: Normal (or close to normal) distribution.

Usage: Used to detect small gradual shifts in the process mean. The chart calculates the cumulative sum of deviations from a target or a reference value over time. It continuously adds the differences between each observed value and the target, allowing the chart to track the cumulative deviation from the target.

Example: The hospital sets a target minimum rate of newborn nursery babies discharged with maternal milk is 80% each month. The CUSUM chart will monitor the cumulative sum of deviations from this target over time.

1.1.2 Recent changes

Chart: Exponentially Weighted Moving Average (EWMA) control chart

Assumption: Normal (or close to normal) distribution.

Usage: Used to monitor the process meanwhile giving more weight to recent observations. The chart computes a weighted average of the observed values, with exponentially decreasing weights assigned to older observations. This means recent observations contribute more to the average than older ones.

Example: The hospital sets a target minimum rate of NICU babies discharged with maternal milk is 60% each month. The EWMA control chart calculates a weighted average of the observed rates, with higher weights given to more recent data points.

1.2 DETECTING LARGE CHANGES

Step 2: Determine the Data Type

- **Discrete or Attribute Data:** This type of data can only take specific values, typically counts of

defective items or events. Examples include the number of medical defects, the number of patients readmitted, or the number of patients with sepsis.

- **Continuous/Variables Data:** This type of data can take any value within a given range or a total count of events that are not defects. Examples include blood loss, weight, or the number of discharged patients.

1.2.1 Continuous Data

Step 3: Select the Control Chart Type

For continuous data, we need to decide on two features: the sample size and the number of subgroups. The combinations of these two features and their impact on selecting a control chart type are described below.

1.2.1.1 Sample size n=1

Chart: Individuals and Moving Range (I-MR) Chart

Assumption: Normal distribution.

Usage: Used when the sample size or subgroup size for each measurement is one.

- I chart monitors the variation of individual measurements from the process mean.
- MR chart monitors the variation between consecutive measurements.

Example: Monitor breastfeeding volume for a newborn baby named Q. We record the volume of milk (in milliliters) Q consumes each day.

1.2.1.2 Sample size 2<=n<10

Chart: X-Bar and R (Range) Chart

Assumption: Normal distribution.

Usage: Used when the sample size is 2 to 10 in each subgroup.

- X-Bar chart monitors the process mean over time.
- R chart monitors variability within the process over time. R represents the range of the sample, calculated as the difference between the maximum and minimum values in a sample.

Example: Monitor breastfeeding volume for a sample of 5 newborn babies (these babies are representative sample of all newborn babies that day). We record the average volume of milk (in milliliters) these babies consume each day.

1.2.1.3 Sample size n>=10

Chart: X-Bar and S (Standard Deviation) Chart

Assumption: Normal distribution.

Usage: Used when the sample size is greater or equal to 10 in each subgroup.

- X-Bar chart monitors the process mean over time.
- S chart monitors variability within the process over time. S represents the standard deviation of the sample.

Example: Monitor breastfeeding volume for newborn babies born on the same day (we assume that there were at least 10 babies born on the same day). We record the average volume of milk (in milliliters) babies consume each day.

1.2.2 Discrete/Attribute Data

Step 3: Select the Control Chart Type

For discrete/attribute data, we need to decide on two features:

1. Whether the number of defects per unit matters.
   a. Multiple defects per unit: it is important how many distinct defects exist per unit.
   b. One defect per unit: it is only important whether a unit is defective or not, and it does not matter how many distinct defects exist per unit.
2. Whether the sample size is constant.

The combinations of these two features and their impact on selecting a control chart type are described below.

1.2.2.1 Multiple defects per unit, constant sample size

Chart: C Chart

Assumption: Poisson distribution.

Usage: Monitor the count of defects per unit when the sample size is constant.

Example: Monitor the number of VLBW and mortalities per 1,000 babies each month.

- A "unit" is a baby. The "defects" are VLBW and mortality. The sample size is 1,000.

1.2.2.2 Multiple defects per unit, varying sample size

Chart: U Chart

Assumption: Poisson distribution.

Usage: Monitor the rate of defects per unit when the sample size varies.

Example: Monitor the rate of VLBW and mortalities among all babies born each month.

- A "unit" is a baby. The "defects" are VLBW and mortality. The sample size is the number of babies born in a specific month.

1.2.2.3 One defect per unit, constant sample size

Chart: NP Chart

Assumption: Binomial distribution.

Usage: Monitor the number of defective items in a sample when the sample size is constant.

Example: Monitor the number of babies discharged without maternal milk per 1,000 babies each month.

- An "item" is a baby. A "defective item" is a baby discharged without maternal milk. The sample size is 1,000.

1.2.2.4 One defect per unit, varying sample size

Chart: P Chart

Assumption: Binomial distribution. For larger sample sizes, the binomial distribution approximates normal distribution due to the Central Limit Theorem.

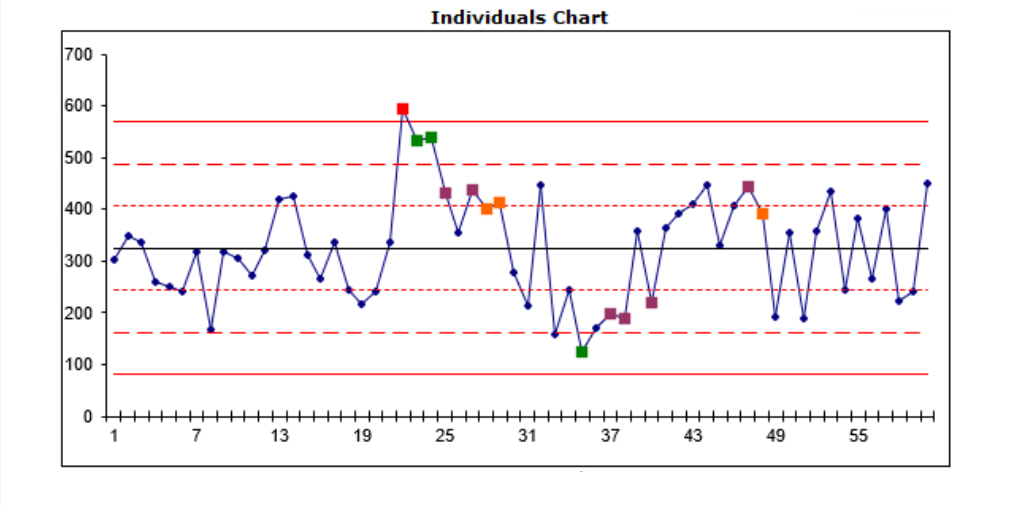
Usage: Monitor the proportion of defective items in a sample when the sample size varies.

Example: Monitor the proportion of babies discharged without maternal milk each month.

- An "item" is a baby. A "defective item" is a baby discharged without maternal milk. The sample size is the number of babies discharged in a specific month.

2.0 STEP-BY-STEP INSTRUCTIONS TO CREATE AN I-MR CHART AND ANALYZE AND MONITOR DATA USING THE EXCEL TEMPLATE

The American Society for Quality provides a ready-to-use Excel template for creating an Individuals and Moving Range (I-MR) chart. The template includes step-by-step instructions for entering your data and automatically generates the chart. Below is a step-by-step guide to use this template to create an I-MR chart for the monthly number of babies discharged over the last five years (see Figure below).



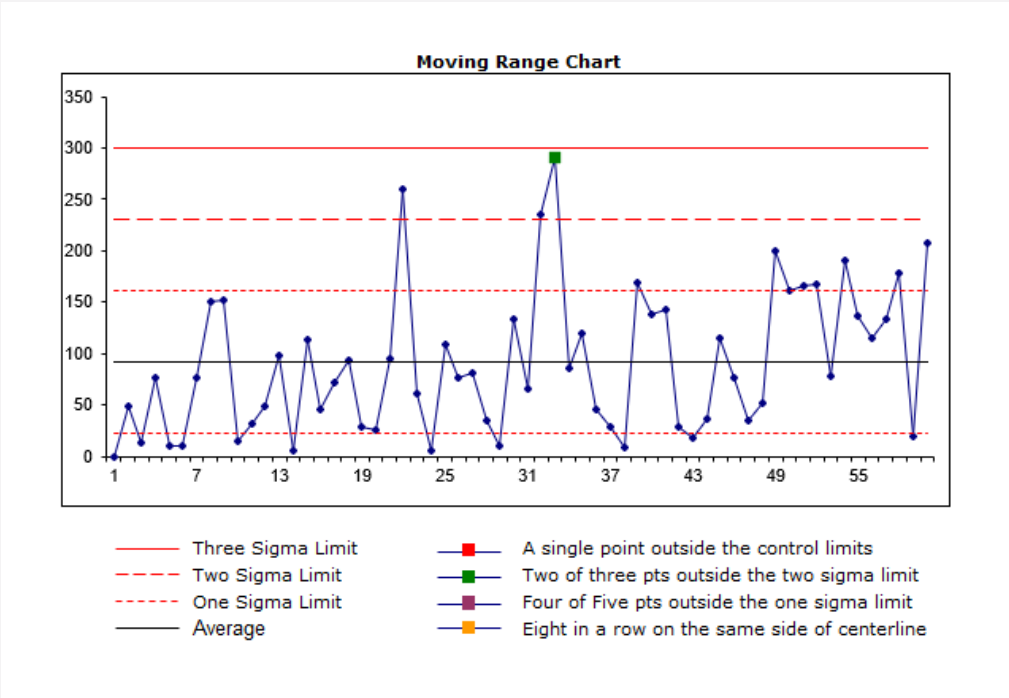


Figure 2. I-MR Chart

Figure 2 shows an I-MR chart, which pairs an Individuals chart (for the raw data) with a Moving Range chart (for variation between consecutive points) to monitor process stability and detect anomalies.

2.1 SELECT THE APPROPRIATE SUBGROUP SIZE

Choose a subgroup size of 1 for individual monthly discharge values.

For this case:

- Number of data points: 60
- Subgroup size: 1
- Number of subgroups: 60

2.2 ENTER MONTHLY DISCHARGE DATA

- Ensure Input up to 200 data points in the data input section of the I-MR chart sheet.
- Do not edit the “Subgroup” column—this auto-populates.

For this case:

- Monthly discharges (60 points) over 5 years × 12 months
- Individuals Chart Average ($\bar{X}$): 324.13
- Moving Range Average ($\bar{MR}$): 91.797
- Sigma-based control limits (±1σ, ±2σ, ±3σ) are calculated automatically.

2.3 ANALYZE CONTROL CHART SIGNALS

Use the chart legend and color-coded markers to identify out-of-control points based on four statistical rules:

Rule 1: A single point beyond control limits

Example:

- Point 22 is above the Upper Control Limit (UCL).
- Indicates a likely special cause variation that should be investigated.

Rule 2: Two out of three points beyond 2σ on the same side

Example:

- Points 23, 24 trigger this rule.
- Suggests a moderate process shift.

Rule 3: Four out of five points beyond 1σ on the same side

Example:

- Point 25 meets this condition.
- Indicates a strong trend or shift.

Rule 4: A run of eight or more points on the same side of the centerline

Example:

- Points 28, 29 are the eight consecutive points above the centerline.
- Suggests a persistent shift or process change.

2.4 MONITOR THE PROCESS OVER TIME

- Continue plotting new data points as they become available (e.g., monthly discharges).
- After adding each new point, observe the I-MR chart for any emerging out-of-control signals based on the four rules.
- Timely detection of unusual patterns enables proactive investigation and intervention.

REFERENCES:

Link to the ASQ control chart

Link to the Control charts study guide overview

Our sample Excel file shows monthly baby discharges.