A STUDY ON THE APPLICATION OF CONTROL CHART IN HEALTHCARE

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DECLARATION

I hereby declare that this project report is based on my original work except for citations and quotations which have been duly acknowledged. I also declare that it has not been previously and concurrently submitted for any other degree or award at UTAR or other institutions.

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APPROVAL FOR SUBMISSION

I certify that this project report entitled **"TITLE TO BE THE SAME AS FRONT COVER, CAPITAL LETTER, BOLD"** was prepared by **STUDENT'S NAME** has met the required standard for submission in partial fulfilment of the requirements for the award of Master of Mathematics at Universiti Tunku Abdul Rahman.

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ABSTRACT

Measuring quality is always a high priority in healthcare as bad or low quality make a difference in terms of patient's life or death. A quality statistical technique such as statistical process control (SPC) charts will be powerful and highly effective in monitoring process improvement and in reducing the sources of variability in healthcare process. Control chart is statistical process control tool that developed to measure the process improvement in manufacturing industry and are recently increasingly being applied in healthcare sector. Examples of applying statistical process control charts in monitoring the ambulance response time, medical device/equipment adverse events and number of patient-safety-related deaths are reviewed.

The main advantage of applying control charts methodology is control charts can determine whether the process is stable and to detect when significant signal or special cause of variation exist. Control charts can help healthcare institutions to prevent wasted investment in any changes that sound great but have no beneficial effect in real improvement. Furthermore, control charts can detect the shift in the process or significant signal from the data pattern faster than other statistical tools. More commonly, control chart can assist the healthcare institutions to select the appropriate or right improvement strategy- whether to search and eliminate special causes to shift process into state of control (if process is out of control) or to put more effort on fundamental process improvement and restructure or redesign the process into desirable direction (if process is in state of control).

When there is greater involvement of human in healthcare, the chances of error are also greater. Control chart helps to identify the source of error by differentiate the special and common cause of variation, each of which require a different healthcare management response. The healthcare institution will then be aware of any abnormal behaviour or out of statistical control condition that take place in process which affected by special causes of variation and corrective or a preventive action could be taken immediately for eliminating the source of variation. By monitoring and supervising a process, this can ensure the process is stable, and consistently operating at its fullest potential.

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LIST OF SYMBOLS / ABBREVIATIONS

x	data/measurement
n	subgroup size
MR	moving range
R	range value
S	standard deviation
C	number of defects in each subgroup
U	defects rate per inspection unit
D	number of defectives units in each subgroup
p	defectives rate per inspection unit

CHAPTER 1

INTRODUCTION

1.1 General Introduction

The healthcare quality and quality improvement are always the main concern in healthcare system as low quality will affect the life or death of patients. In addition, the demand for quality healthcare services is expected to increase in the future due to the global demographic shifts such as the increase in the pace of population aging, lifestyle disease and lifestyle expectancy (Malaysian Investment Development Authority, 2018; World Health Organization, 2018). Furthermore, patients are being more aware of their rights in term of healthcare and concerning about the quality of the provided healthcare service nowadays (Gupta and Rokade 2016). Thus, it is important for the provider to create a safe and effective healthcare system because poor healthcare quality can affect life or death of patients.

Researcher Arthur (2016) has revealed that around 6% of the patients will be permanently disabled and 1% of the patients will die due to the medical error. In addition, the research also indicated that around 15% of the diagnoses are incorrect; 5% to 10% of the admitted patients acquired an infection during treatment; 50% of the patients are suffered preventable harm while receiving care in hospital and 3% of the patients have an incorrect ID band. Hence there is necessary to continuously control, monitor and improve the performance of healthcare so that adverse effect can be reduced to the smallest degree. In order to meet the patient's satisfaction, healthcare system need an investment to improve their performance. Improvement of healthcare performance require to apply changes in the processes system; however, not all changes lead to desired results or results in improvement. To monitor the performance or to identifying whether there are beneficial changes; healthcare institutions or researchers first need to determine the key indicators, then collect a proper amount of data; and the last is to analyse and interpret these data. This study will focus on the analysing and interpreting of data by using statistical process control (SPC) tool. A quality statistical technique such as statistical process control (SPC) charts will be powerful and highly effective in monitoring process improvement, and in reducing the sources of variability in healthcare process (Suman and Prajapati, 2018). The SPC chart was initially used in manufacturing industries to improve the process and quality

of products. In recent times, SPC tools is increasingly being applied in service industries such as healthcare (Odetunmibi, and Oluwadare, 2015; Suman and Prajapati, 2018). The aim of this study is to provide an overview of SPC theory and to examine the application of SPC charts by providing examples of control charts implementation to common issues in healthcare industry. This paper provides information on concept, interpretation and selection of the appropriate control chart; and a few examples of applying control charts to monitor healthcare performance are reviewed.

1.2 Importance of the Study

The study will establish an understanding on application of control chart in healthcare. Moreover, the study could be importance to the following:

Healthcare Institutions. The information presented in the study will assist healthcare institutions in monitoring their process performance and preventing them from investing more resources and time in implementing unproductive or ineffective change throughout the system.

Healthcare Practitioners. The study will provide the guidelines and examples for practitioners to construct statistical process control chart in monitoring healthcare delivery and improvement.

Future researchers. The study presented can used as a reference data for conducting new studies or testing other relevant findings. This study will help as their cross-reference that provide them an overview or background of application of statistical process control chart in healthcare industry.

1.3 Problem Statement

Variation in efficiencies and healthcare processes has become a major topic for healthcare researchers, as it is one of the greatest challenges faced by healthcare organization in performance improvement work nowadays (Love and Ehrenberg, 2014). Dr. William Edwards Deming, a well-known statistician and physician, stated that “Uncontrolled variation is the enemy of quality” (Chang and Paul, 2012). He suggested that the key to improve the performance and quality is to reduce statistical variation. The rise of studies on the healthcare sector is further recognizing the relationship between improving performance and reducing variation (Love and Ehrenberg, 2014).

Thus, a continuous quality improvement of healthcare system requires the measuring and understanding of process variation (Faltin, Kenett, and Ruggeri, 2012). It is significant to remove irrelevant process variation and moving the clearly defined metrics toward their expected standards. For instances, the significant variables that involve in healthcare sector include waiting time, patient satisfaction level, infection rate, medical error, mortality rate, emergency service response time and so forth. Hence, the monitoring, controlling, studying and analysing of such variables can lead to substantial improvement in term of quality. Within this framework, a quality statistical technique such as statistical process control (SPC) charts will be effective in studying and analysing the process variation; monitoring and controlling healthcare performance; and identifying whether there is quality improvement or deterioration (Faltin, Kenett, and Ruggeri, 2012). Control chart is statistical process control tool developed by Walter Shewart, a physicist, to determine whether the variation in the manufacturing process is consistent; that is, to determine whether the process is in the state of control (Owen, 2013). In recent times, the application of control chart has received growing interest in healthcare sector to monitor, control and improve the healthcare process performance. However, since SPC is comparatively new in healthcare sector and it is not common being introduced in medical statistic course or texts; there is a need to conduct a research to study the application of control chart in healthcare.

1.4 Aims and Objectives

The aim of this research study is to provide an overview of SPC theory and to explore the application of SPC charts in monitoring healthcare performance by providing examples of control charts implementation to common issues in healthcare industry. To achieve this aim, the objectives covering following issues:

1. To study on the application of different control charts in monitoring healthcare performance.
2. To identify and select the most appropriate control chart based on the data type to determine whether the process is out of control by identify any variation occurred due to the special cause.
3. To investigate the cause of the special variation, when appropriate, act to eliminate or remove it.

4. To further improve the quality performance by examining the entire process systematically.

1.5 Scope and Limitation of the Study

The purpose of this research is to conduct a study of control charts application in monitoring healthcare performance. The research comprises the study of different types and uses of control chart in monitoring healthcare performance and then able to identify the most appropriate control chart in relation to the healthcare performance. The evaluation of healthcare performance is completely based on the existing secondary data within the healthcare institutions. This research is aimed to help the healthcare organization to reduce variability; and save the considerable time and associated operating costs through the implementation of performance monitoring control chart.

A secondary data analysis was used in this study due time constraint and cost-effectiveness. In addition, it is recommended to have 20-25 data points to construct the control limits (Montgomery, 2009). However, we did not take part in the process to collect the data; thus, we have no control over what and how the data have been collected. Thus, we are not able to increase the number of data points. Furthermore, this study only considered the seven types of control charts methodology that will have frequent applied in healthcare. The provided examples of the application of control charts to common issues in healthcare industry in this research only covers three type control charts.

1.6 Contribution of the Study

This research will denote the significance of control chart as a powerful monitoring tool in supervising and improving the process performance over time by studying and analysing statistical variation and its source. When there is higher participation or involvement of human in healthcare, the chances of mistake or error are also higher. Control chart helps to identify the cause of error by differentiate the common and special cause of variation, each of which require a different healthcare management response. The healthcare institution will then be aware of any abnormal behaviour or out of statistical control condition that take place in process which affected by special causes of variation and corrective or a preventive action could be taken immediately

for eliminating the source of variation. By monitoring and supervising a process, this can ensure the process is stable, and consistently operating at its fullest potential.

The developed control chart has brought a lot of advantages toward healthcare sector as it provides convenience to healthcare institutions to keep the organizations from investing further resources and time in training employee and implementing an unproductive change which may lead to inappropriate decision making throughout the organizations. The control chart is one of the quality improvement technique which can be applied to deliver continuous improvement. A quality healthcare system is crucial for a country as it denote the population has the access to combat illness; it supplies a nation with the needed stability to build reliable workforce that optimize productivity and lead to a more unified country. This make a significant contribution to economic progress and create a thriving economy.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

The purpose of this chapter is to review the related research and literature relevant to the application of statistical process control (SPC) charts in healthcare. Since 1990s, the growth in the quality and quantity of the study on the application of statistical process control (SPC) techniques in healthcare sector has provided increasing evidence that control chart have play an effective role in monitoring and improving healthcare processes and performance such as mortality rate, infection rate, waiting time of various sorts and percentage of errors in hospital (Bush, 1991; VanderVeen, 1992; Finison, Finison and Bliersbacl, 1993; Finison and Finison 1996; Quesenberry, 2000; Curran, et al., 2008). This chapter first discuss the theory of SPC, then followed by concept of control chart. Then, the next part is focusing on interpretation and test rule of control chart. The last part discusses the type of data and method on selection of the right control chart.

2.2 Statistical Process Control (SPC) Theory

The fundamental of Statistical Process Control (SPC) and the associated tool of Control Chart was developed by Dr Walter Andrew Shewhart, a physicist, to improve the industrial manufacturing process (Best and Neuhauser, 2006). Dr Walter Shewhart was born on 18 March 1981 in New Canton, Illinois, United States. He received his bachelor's degrees in 1913 and master's degrees in 1914 from University of Illinois and then he was awarded his physic doctorate from the University of California in 1917 (Best and Neuhauser, 2006).

Shewhart joined the Inspection Engineering Department of Western Electric Company's in 1918, he was given a task on statistical tools which is applying statistical sampling methods to examine the potential for industry and identify when a corrective action must be taken to the process (Best and Neuhauser, 2006; Owen, 2013). On 16 May 1926, Shewhart prepared a memorandum to his superior, Dr R.L. Jones, he included a chart and the details of the chart concept (Levin 2005; Owen 2013). The chart included in the memorandum was known later as control chart, and this was the start of the SPC.

Shewart published his results in 1931 as *Economic Control of Quality of Manufactured Product*. In his book, he revealed that adoption of statistical quality control technique in manufacturing industrial is extremely useful (Owen, 2013). The control chart is widely used in manufacturing industry for many decades, since the first introduced by Steward in 1924. Within the continuous quality improvement process framework, the control charts are growingly being applied to service industry including healthcare to evaluate process stability and process capability; to facilitate in process understanding and to recognize changes indicate whether quality improvement or deterioration (Finison, Finison and Bliersbacl, 1993; Faltin, Kenett, and Ruggeri, 2012).

2.3 Concept of Control Chart

Statistical Process Control (SPC) is a philosophy of continual improvement that work on various statistical tools to monitor, control and improve the product and process; and to identify and solve the process problems. Wisner (2005) and Mohammed, Worthington and Woodall (2008) stated the major statistical tool of SPC is known as the Statistical Control Chart, the application of SPC generally require the production of control chart. According to Finison, Finison and Bliersbac (1993) and Mohammed, Worthington and Woodall (2008), the control chart shows how an output or process varies over time; the main objective of applying control chart is to identify whether the process is in state of control or out of control and whether the source of variation is due to common causes (also known as common or random causes) or special causes (also known as assignable causes). Moreover, Suman and Prajapati (2018) indicated that the process improvement does not automatically lead by the application of the control. There is the duty of management team linked with the process to identify the special causes of variation and revise it.

There are two sources of process variation always quoted, which are common cause variation and special cause variation (Mohammed, Worthington and Woodall, 2008). Common cause variation refers to the variation that exists as a natural in a consistent process; it is unavoidable. It is expected to occur based on the underlying statistical distribution; if its parameter such as mean and standard error tend to be constant over time (Lighter, 2010). Moreover, the common causes of variation are common to any process that are stable, it occurs in nature and can be revealed only through the consistent learning of the process and reduce by redesigning the system

(Finison, Finison and Bliersbacl, 1993). For example, within a population of healthy patients, the common variation in blood pressure is an outcome of basic human physiology, while the common variation in surgical wound infection rate is an outcome of factors such as surgical training and nursing practises (Benneyan, Lloyd and Plsek, 2003).

Special cause variation refers to the variation which is unnatured due to changes and occurrences that previously have not been existing in the process as a regular basic (Benneyan, Lloyd and Plsek, 2003). It needs to be examined and find out what is the source and then take a proper action to remove it. If the process consists only common causes variation, and there is no special causes variation are indicated; the process is said to be in control (Finison, Finison and Bliersbacl, 1993). By observing the variation, there are two general approaches can be used to improve the processes. If the process contains only common cause variation, it will remain to generate the identical outcome within the statistical limits, unless the process system is restructured or redesigned. However, if the process contains special cause variation, it is unpredictable and unstable; then, it should be enhanced by first remove the special causes to shift the process into the state of control. Thus, if the purpose is only to sustain the existing level of performance, special causes variation must be prevented and removed (Benneyan, Lloyd and Plsek, 2003). However, if the objective is to improve the quality performance, the elimination of special cause variation and the reduction of the remaining common cause variation are both needed to be conducted; then, implementing a change or suggesting interventions to redesign the process system to a desirable direction.

Douglas (2009) stated the use of statistical process control charts usually described as involving two stages or phases (Phase I and Phase II application), with two different objectives. In initial phase, Phase I, a retrospective analysis is conducted on historical data to construct the trial control limits or a baseline to determine whether the process is in state of control and to assess if the control limits can be adopted to monitor the future performance. Control charts in phase I mainly assist to shift the process into the state of control, which is the crucial stage of process control. Before process monitoring can start in Phase II, a phase I application or analysis must be performed if the parameters of the process are unspecified. The process control charts in phase II are used to monitor the process and assume that a sample for reference can

be obtained from corresponding Phase I application or analysis, from which the trial control limits are estimated.

According to Benneyan, Lloyd and Plsek (2003), control chart can detect the special cause variation faster than other SPC tools; and thus, it is one of the most valuable tools for assessing the productiveness of a process and ensuring the sustainability of the continuous improvement in process over time. Woodall (2006) have conducted a research on the application or implementation of control chart in healthcare sector, he found out the use of control chart in healthcare sector is different from manufacturing industrial practise. For instances, the attribute data is more commonly used in healthcare sector than in manufacturing sector. In addition, there is more use of charts based on time or counts between failure.

2.4 Interpretation of a Control Chart

A control chart contains two parts: (1) a plot of series of data in time order, and (2) with three additional horizontal lines – the centre line (mean or average), the upper control limit (UCL), and the lower control limit (LCL). According to the Shewart and other statistician, the upper and lower control limit are set as ± 3 standard deviations (SDs) from the mean for detecting the meaningful or significant changes in process performance. When the data point falls randomly between the upper and lower control limits, the process is assumed to be displaying common causes of variation and then is considered in statistical control. In general, if the underlying distribution is stable, we can expect that nearly all data point will fall within ± 3 standard deviations from means; thus, process is considered in state of control. Shewhart (1931) defined a process is out of control when there is any point went above the upper limit or below the control limit. Then, there are other supplementary run rules have been developed to further describe the out-of-control process (Finison, Finison and Bliersbacl, 1993). These supplementary run rules are stated in the Test Rule section below.

2.5 Test Rule for Control Chart

A common set of tests was suggested for special cause variation, in which a process is out of control (Hart and Hart 1989; Suman and Prajapati, 2018). These rules are:

1. If any points above a UCL or below an LCL.
2. If two of three successive points fall beyond the two sigma control limits on the same side of the centre line.

3. If four of five successive points fall beyond the one sigma control limits on the same side of the centre line.
4. If eight or more successive points in a row fall on either side of centre line.
5. A trend of six or more successive pointes gradually increasing or decreasing.
6. An obvious cyclic behaviour or systematic nature of the plot indicated that special causes exist, and process is out of control.

2.6 Types of Data

To create a control chart, there must be availability of data. Data are categorized into two types - variables data and attribute data (Suman and Prajapati, 2018). Variable data or continuous data involve measurement on continuous scale, for instances, weight, height, body temperature and time spent in waiting for consultation. Attribute data or discrete data involve counts or classification, for instances, number of patients fall, number of patients waiting for consultation, mortality rate and compliance or not compliance with medical standard. Finison, Finison and Bliersbach (1993) stated the attribute data can be either counts of the number of defects or counts of defectives. Defect data is referring to a part or feature of a product or a unit of service that fail to achieve customer need. The defect on the service or products are counted and the number are recorded. The event can happen multiple times to the same item such as there can be no defect, one defect or a few defects in each unit production. For example, counting the number of defects which can be happen more than once such as the number of patients falls and the number of dietary tray error. However, defective data is referring to the entire unit of production acceptable or not acceptable. The event can only happen once to the same item. Defective data can be only binary such as Yes or No; for instance, classifying an item as whether it meet the standard or not such as deaths and compliance/not compliance with medical standard. Table 1 indicates the differences between count defect and defectives data.

Table 2.1: Differences between Count Defect and Defectives Data

	Count Defects	**Defectives**
Machine 1	1	Not Acceptable
Machine 2	3	Not Acceptable
Machine 3	0	Acceptable
Machine 4	2	Not Acceptable
Machine 5	0	Acceptable
Machine 6	2	Not Acceptable
Machine 7	2	Not Acceptable
Machine 8	0	Acceptable
Machine 9	2	Not Acceptable
Machine 10	0	Acceptable
Total	12	6 Not Acceptable
Fraction/Rate	12/10 = 1.2	6/10 = 0.60

2.7 Selection of the right Control Chart

There are several empirical studies on the implementation of control chart have given advice on selection and design in healthcare applications. Amin (2001) stated that among the various types of control chart, seven charts are most commonly used to monitor the process performance in healthcare sector (Amin, 2001). The appropriate chart to applied is depend largely on the type of data that being plotted and analyzed (Finison, Finison and Bliersbacl, 1993; Mohammed, Worthington and Woodall, 2008; Suman and Prajapati, 2018). There are three basic control charts designed for variable data: XmR chart, $\bar{X}$ and R chart and $\bar{X}$ and S charts; and four basic control charts designed for attributes data: U chart, C chart, P chart and NP chart (Amin, 2001). These control charts are highly suggested for Phase I application (Mohammed, Worthington and Woodall, 2008).

Suman and Prajapati (2018) have conduct a research to study the literature reviews on the implementation of SPC and control chart methodology in healthcare sector, they discovered that $\bar{X}$ and R chart; and $\bar{X}$ and S charts are the mostly applied in the healthcare implementations for variable data. Moreover, P chart and U chart are commonly used in healthcare for attribute data.

2.7.1 Control Charts for Variable Data

Benneyan (1998a; 1998b; 2008) suggested that when the variable data is normally distributed, $\bar{X}$ chart and S chart should be used together. In addition, Amin (2001)

suggested that the appropriate chart can be selected by examining the subgroup sizes. If the subgroup size for each data point equal to one, e.g., waiting time of a patient for consultation, then use of XmR chart (X chart and Moving Range chart) generally is recommended. If the subgroup size for each data point is small (more than 1 and less than or equal to 10) and equal in size, e.g., waiting time of 7 patients for consultation, then use of $\overline{X}$ and R chart generally is suggested. If the subgroup size for each data point is large (more than 10) or unequal in sizes, e.g., waiting time of 20 patients for consultation, then use of $\overline{X}$ and S chart generally is recommended.

2.7.2 Control Charts for Attribute Data

Benneyan (1998a; 1998b; 2008) suggested that when the attribute data is generated by Poisson distribution, either C chart or U chart should be used. When the count data is from Binomial distributions, either P chart or NP chart should be used. In addition, Amin (2001) proposed that the selection of the attribute data chart is depend on whether the data points are counts of the number of defects or counts of defectives. If the data derived from counts of defects, either C chart or U chart can be used. If the subgroup size is constant for each data point and the data derived from counts of defects, e.g., each data point represents the number of falls in a sample of 15 patients, then a C chart is typically suggested. If the data is based on rate of defects or defect per unit, e.g., rate of patients falls per 100 patient days or the events per monthly discharge, then a U chart is more appropriate. The subgroup sizes of U chart can be either constant or variable size. However, the subgroup sizes are seldom constant in healthcare.

If the data derived from counts of defectives, either NP chart or P chart can be used. If the subgroup sizes are constant for each data point and data are defectives or classification data, e.g., the number of medical devices non-compliance with medical standard out of 100 devices per month, then a NP chart is generally recommended. If the data is based on rate of defectives or percent defectives, e.g., monthly mortality rate because the total number of deaths will differ from month to month, then a P chart is more appropriate. The subgroup sizes of P chart can be either constant or variable size. However, the subgroup sizes are seldom constant in healthcare. The Figure 2.1 shows the different types of data and corresponding control charts that available.

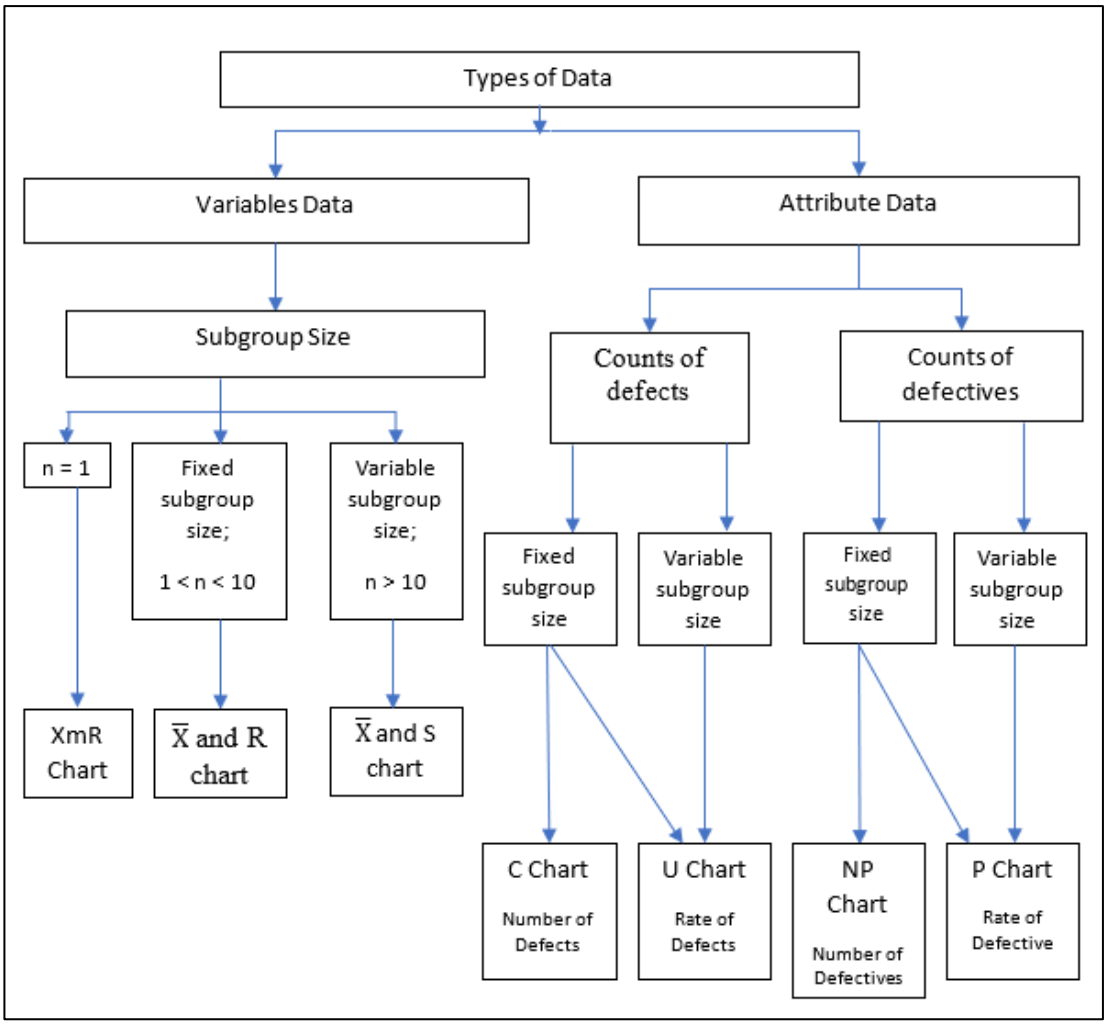

Figure 2.1: The Types of Data and Control Chart (Source : Finison, Finison and Bliersbacl, 1993 ; Suman and Prajapati, 2018).

CHAPTER 3

METHODOLOGY AND WORK PLAN

3.1 Introduction

Research methodology will indicate the procedures of constructing the different type of control chart in monitoring the healthcare performance. This study adopts a quantitative technique to secondary data analysis of existing data sets from healthcare sector. A set of data point or observation, which also known as subgroup, from time to time is sampled from the process, and parameter such as the ambulance response time, rate of medical devices adverse events per incident and the number of patient-safety-related deaths are estimated from each subgroup and then plotted on an different appropriate control chart in chronologic order with three horizontal lines (the centre line (CL), the upper control limit (UCL) and lower control limit (LCL)). The selection of the appropriate of control chart is based on the type of data that analyse. The centre line and control limits are used to detect the significant statistical changes in the present healthcare performance, whether special cause variation exist (refer to Test Rule in Chapter 2.5). The centre line is set equal to the arithmetic mean of the plotted data, and control limits are set equal to centre line plus and minus three standard deviations of the plotted data. This chapter will include the formula and construction methods of the seven types of control charts that will have frequent applied in healthcare. Furthermore, to determine the impact of a process change, whether the improvement has a positive impact, we can freeze the centre line and control limits from the historical data (Phase I application) and continue to plot the new data on the control chart (Phase II application). A change or intervention in a quality improvement process are an effort that done intentionally and consciously to introduce a special cause of variation (Benneyan, Lloyd and Plsek, 2003). Thus, signal of special cause of variation illustrate that the new process is significantly different from historical process. Then, we can revise or recalculate the control limit using the new data. The consistency of performance in different chart such as XmR chart; U Chart and NP chart in monitoring the healthcare performance will be further discussed in the next chapter to identify the process trend with the aim to improve the quality of performance in healthcare sector.

3.2 Formula and Construction Methods for Variable Data Control Charts

3.2.1 XmR Chart

The XmR chart is useful if each subgroup consists of an individual unit; which is, the subgroup size that used for process monitoring is equal to one. XmR chart consist of two charts which are the X chart (or Individual chart) and Moving Range (MR) chart. X chart shows the individual performance; which is a control chart of the value of *n* observations, $X_1, X_2, \ldots, X_n$ and the MR-chart indicates the variability between one successive point and the subsequent; which is a control chart of the moving ranges from the data (Mohammed, Worthington and Woodall, 2008). Thus, there will be one fewer data point in MR chart than the X chart.

To set up the MR chart:

(i) Compute the moving range (MR); which is absolute value of the differences between the successive values such as $MR_i = |X_i - X_{i-1}|$.

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \overline{MR} = \frac{\sum_{i=2}^{n} MR_i}{n-1}$$

$$UCL = D_4 \text{ x } \overline{MR} = 3.267 \text{ x } \overline{MR}$$

$$LCL = D_3 \text{ x } \overline{MR} = 0 \text{ x } \overline{MR}$$

(iii) Plot the MR_i, CL, UCL and LCL values on the same graph, and put the graph below of X chart.

To set up the X chart:

(i) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$UCL = \bar{X} + 3\frac{\overline{MR}}{d_2} = \bar{x} + 3\frac{\overline{MR}}{1.128} = \bar{X} + 2.66\, x\, \overline{MR}$$

$$LCL = \bar{X} - 3\frac{\overline{MR}}{d_2} = \bar{X} - 3\frac{\overline{MR}}{1.128} = \bar{X} - 2.66\, x\, \overline{MR}$$

(ii) Plot the X_i, CL, UCL and LCL values on the same graph, and put the graph above of MR chart.

3.2.2 The $\overline{X}$ and R chart

The $\overline{X}$ and R chart are useful if subgroup size for each data point is constant and small, which is more than one and equal or less than 10.

Suppose $X \sim N(\mu, \sigma^2)$, there are m subgroups, each subgroup containing n observations.

To set up the R chart:

(i) Compute the range value (R) for each subgroup,

$R = \max(X_1, X_2, \dots, X_n) - min(X_1, X_2, \dots, X_n)$.

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{R} = \frac{\sum_{i=1}^{m} R_i}{m}$$

$$UCL = D_4\bar{R}$$

$$LCL = D_3\bar{R}$$

D_3 and D_4 refer to the factors in $\boldsymbol{D_3}$ and $\boldsymbol{D_4}$ column respectively that corresponds to the subgroup size in Figure 2.

(iii) Plot the R_i, CL, UCL and LCL values on the same graph, and put the graph below of $\overline{X}$ chart.

To set up the $\overline{X}$ chart:

(i) Compute the average value $\overline{X}$ of each subgroup.

$$\overline{X} = \frac{X_1 + X_2 + \cdots + X_n}{n}$$

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{\bar{X}} = \frac{\sum_{i=1}^{m} \bar{X}_i}{m}$$

$$UCL = \bar{\bar{X}} + A_2\bar{R}$$

$$LCL = \bar{\bar{X}} - A_2\bar{R}$$

A_2 refer to the factors in $\boldsymbol{A_2}$ column that corresponds to the subgroup size in Table 3.1. If LCL < 0, then set LCL at zero.

(iii) Plot the $\overline{X}_i$, CL, UCL and LCL values on the same graph, and put the graph below of $\overline{X}$ chart.

Table 3.1: Table of Constants for $\overline{X}$ and R chart (Source: Murdoch and Barnes, 1998).

	$\overline{X}$ chart	**R chart**	
Subgroup Size	**Factors for Control Limit**	**Factors for Control Limit**	
	$\boldsymbol{A_2}$	$\boldsymbol{D_3}$ **(LCL)**	$\boldsymbol{D_4}$ **(UCL)**
2	1.880	0	3.267
3	1.023	0	2.574
4	0.729	0	2.282
5	0.577	0	2.114
6	0.483	0	2.004
7	0.419	0.076	1.924
8	0.373	0.136	1.864
9	0.337	0.184	1.816
10	0.308	0.223	1.777

3.2.3 The $\overline{X}$ and S chart

The $\overline{X}$ and S chart are useful if subgroup size for each data point is variable or large (more than 10).

Suppose we have K subgroups, each of size n_i.Let X_{ij}be the measurement in the j^{th}sample of the i^{th} subgroup.

Let

The i^{th} subgroup, $n_i =$ number of observations in the i^{th} subgroup.

$\overline{X}_i =$ average of the i^{th} subgroup

$S_i = i^{th}$ subgroup standard deviation

To set up the S chart:

(i) Compute the average value $\bar{X}$ of each subgroup.

$$\bar{X}_i = \frac{\sum_{j=1}^{n_i} X_{ij}}{n_i}$$

(ii) Compute the standard deviation (S) for each subgroup.

$$S_i = \sqrt{\frac{\sum_{j=1}^{n_i}(X_{ij} - \bar{X}_i)^2}{n_i - 1}}$$

(iii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{S} = \left[\frac{\sum_{i=1}^{m}(n_i - 1)S_i}{\sum_{i=1}^{m}(n_i - 1)}\right]^2$$

$$UCL = B_4\bar{S}$$

$$LCL = B_3\bar{S}$$

B_3 and B_4 refer to the factors in $\boldsymbol{B_3}$ and $\boldsymbol{B_4}$ column respectively that corresponds to the subgroup size in Figure 3.

(iv) Plot the S_i, CL, UCL and LCL values on the same graph, and put the graph below of $\bar{X}$ chart.

To set up the $\bar{X}$ chart:

(i) Compute the average value $\bar{X}$ of each subgroup, $\bar{X} = \frac{X_1 + X_2 + \cdots + X_n}{n}$.

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{\bar{X}} = \frac{\sum_{i=1}^{m} n_i\bar{X}_i}{\sum_{i=1}^{m} n_i}$$

$$UCL = \bar{\bar{X}} + A_3\bar{S}$$

$$LCL = \bar{\bar{X}} - A_3\bar{S}$$

A_3 refer to the factors in $\boldsymbol{A_3}$ column that corresponds to the subgroup size in Figure 3. If LCL < 0, then set LCL at zero. Control limits are calculated using sample size n_i in each individual subgroup. Thus, the control limits lines are specific for each data point and do not appear as a straight line

(iii) Plot the values of $\overline{X}_i$, CL, UCL and LCL on the same graph, and put the graph below of $\overline{X}$ chart.

Table 3.2: Table of Constants for $\overline{X}$ and S chart (Source: Murdoch and Barnes, 1998).

	$\overline{X}$ chart	**S chart**	
Subgroup Size	**Factors for Control Limit**	**Factors for Control Limit**	
	A_3	B_3 (LCL)	B_4 (UCL)
11	0.927	0.321	1.679
12	0.886	0.354	1.646
13	0.850	0.382	1.618
14	0.817	0.406	1.594
15	0.789	0.428	1.572
16	0.763	0.448	1.552
17	0.739	0.466	1.534
18	0.718	0.482	1.518
19	0.698	0.497	1.503
20	0.680	0.510	1.490
21	0.663	0.523	1.477
22	0.647	0.534	1.466
23	0.633	0.545	1.455
24	0.619	0.555	1.445
25	0.606	0.565	1.435

3.3 Formula and Construction Methods for Attribute Data Control Charts

3.3.1 C Chart and U chart

The variable of interest is the counts of defects or rate of defects per unit.

Since the subgroup size (n) is large and the probability for the occurrence of each defect (p) is small, Poisson distribution is used to model the number of defects.

Let X be the number of defects,

If X ~ Poisson (μ), then $P(X = x) = \frac{e^{-\mu}\mu^x}{x!}$, $x = 0,1,2, \ldots$

And E(X) = μ, Var(X) = μ.

C Chart

C Chart is useful if the data derived from counts of defects and the subgroup size is constant for each data point.

Suppose there are m subgroups, each subgroup containing n inspection units. Let C_i= number of defects in i[th] subgroup, C_i ~ Poisson (μ), $i = 0,1,2, \dots, m$ where μ > 0 is the mean of defects for each subgroup

$$\mathrm{P}(C_i) = \frac{e^{-\mu}\mu^{C_i}}{C_i\,!}, \qquad C_i = 0,1,2, \dots$$

and $E(C_i) = \mu$, $Var(C_i) = \mu$.

To set up the C chart:

(i) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{C} = \frac{\sum_{i=1}^{m} C_i}{m}$$

$$UCL = \bar{C} + 3\sqrt{\bar{C}}$$

$$LCL = \bar{C} - 3\sqrt{\bar{C}}$$

If LCL < 0, then set LCL at zero.

(ii) Plot the C_i, CL, UCL and LCL values on the same graph.

U Chart

U Chart is useful if the data derived from average number of defects per inspections unit or rate of defects per unit and the subgroup size is variable for each data point. It considers the subgroup size for each data point and use this subgroup size in generating its control limits. Thus, the lines of control limits are specific for each data point and do not occur as a straight line. Because the subgroup size varies for each data point, these data element must reflect a rate not a count.

Suppose there are m subgroups, each subgroup containing n_i inspections units. Let U_i= average number of defects per inspections unit or rate of defects per unit in i[th] subgroup.

$U_i = \frac{C_i}{n_i}$ where C_i = number of defects in i[th] sample of n_i inspections unit.

C_i~ Poisson (nμ) where μ is mean of defects in one unit.

To set up the U chart:

(i) Calculate the rate of defects per unit U_i in each subgroup, $U_i = \frac{C_i}{n_i}$.

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$$

$$UCL = \bar{U} + 3\sqrt{\frac{\bar{U}}{n_i}}$$

$$LCL = \bar{U} - 3\sqrt{\frac{\bar{U}}{n_i}}$$

If LCL < 0, then set LCL at zero. The $\sqrt{\frac{\bar{U}}{n_i}}$ will vary as the subgroup size for each data point changes.

(iii) Plot the U_i, CL, UCL and LCL values on the same graph.

3.3.2 P Chart and NP chart

The variable of interest is the counts of defective or rate of defective per unit. If a random sample of n units is selected, let D_i be the number of units that are defectives in i[th] subgroup. Since the defective data can be only binary, Binomial distribution is used to model the number of defectives.

$$D_i \sim \text{Binomial (n, p)} \qquad i = 0,1,2,\dots,m$$

where p is the probability of defective item

$$\text{P}(D_i = \text{x}) = {}^{\text{n}}\text{C}_{\text{x}}\, p^x (1-p)^{n-x} \qquad \text{x} = 0,1,2,\dots,\text{n}$$

And $E(D_i) = np$, $Var(D_i) = np(1-p)$.

P Chart

P chart is useful if the data is based on rate of defectives or percent defectives and the subgroup size vary for each data point. Similar to U chart, the lines of control limit take this variation into consideration. Therefore, the control limits do not occur as a straight line. Since the subgroup size varies for each data point, these data point must a rate not a count.

Suppose there are m subgroups, each subgroup containing n_i inspections units. The defective rate for i[th] subgroup, $\hat{p}_i = \frac{D_i}{n_i}$.

The mean and variance are:

$$E(\hat{p}_i) = \mathrm{E}\left(\frac{D_i}{n}\right) = \frac{1}{n}E(D_i) = \frac{1}{n}(np) = p$$

$$Var(\hat{p}_i) = Var\left(\frac{D_i}{n}\right) = \frac{1}{n^2}Var(D_i) = \frac{1}{n^2}\big(np(1-p)\big) = \frac{p(1-p)}{n}.$$

<u>To set up the P chart:</u>

(i) Calculate the rate of defective per unit $\hat{p}_i$ in each subgroup, $\hat{p}_i = \frac{D_i}{n_i}$.

(ii) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = \bar{p} = \frac{\sum_{i=1}^{m} D_i}{\sum_{i=1}^{m} n_i}$$

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$$

If LCL < 0, then set LCL at zero. The $\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$ will vary as the subgroup size for each data point changes.

(iii) Plot the $\hat{p}_i$, CL, UCL and LCL values on the same graph.

NP Chart

NP chart is useful if the data is based on count of defectives and the subgroup size constant for each data point.

Suppose there are m subgroups, each subgroup containing n inspections units. Let D_i be the number of units that are defectives in i[th] subgroup.

D_i ~ Binomial (n, p) $\quad i = 0,1,2,\dots,m$

and $E(D_i) = np$, $Var(D_i) = np(1-p)$.

For fixed subgroup size n, the defective rate for i[th] subgroup $\hat{p}_i = \frac{D_i}{n}$.

The average defective rate $\bar{p} = \frac{1}{m}\sum_{i=1}^{m}\hat{p}_i = \frac{\sum_{i=1}^{m} D_i}{mn}$.

Thus, $D_i = n\hat{p}_i$ and the average number of defectives is $\frac{\sum_{i=1}^{m} D_i}{m} = n\bar{p}$.

To set up the NP chart:

(i) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

$$CL = n\bar{p} = \frac{\sum_{i=1}^{m} D_i}{m}$$

$$UCL = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$LCL = n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$$

If LCL < 0, then set LCL at zero.

(ii) Plot the $n\hat{p}_i$, CL, UCL and LCL values on the same graph.

3.4 Research Methodology

This research will conduct secondary data analysis of qualitative data in healthcare sector. This part will show how healthcare can use the control chart methodology to identify the process trend and to determine the impact of a process change. First, we need to identify and defining the key indicators of the secondary data. Second, we abstract or collect the relevant data from the NHS England. Third, we need to select an appropriate control chart based on the data type to analyse and interpret the data. To analyse the data, we need to determine trial control limits or baseline parameters based on the historical data (process before the time of a change) in order to identify the impact of a process change. Before we freeze the centre line and control limits from the historical data (Phase I application), we need to ensure the process of baseline data is stable, if there is any out-of-control signal detected, we need to shift the baseline process into state of control. If the process is stable, then the limits from baseline data can be freeze and continue to plot the new data on the control chart to test whether a process change has improved the stable process (Phase II application). If there is an out-of-control signal detected, it shows that new process is significantly different from historical process. Then, we can recalculate the new control limit by using the new data (data after the time of a change).

3.5 Research Work Schedule

The figure 3.1 indicate the work schedule for this research project.

		Work Scheldure/Timeline																												
		1st Semenster of 2019													2nd Semenster of 2019															
		Jan			Feb				Mar				April			May	June				July				August					
Stage	Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	Literature Review																												
2	Introduction																												
3	Objectives																												
4	Problem Statement																												
5	Methodology																												
6	Data Discussion																												
7	Limitation																												
8	Conclusion																												
9	Draft																												
10	Refinement																												
11	Turnitin																												
12	Submission Report																												
13	Presentation																												

Figure 3.1: Work Schedule/Timeline for research project

CHAPTER 4

EXAMPLES – RESULTS AND DISCUSSIONS

The control chart, which developed for manufacturing process, are now increasingly being applied in healthcare sector to monitor and control the healthcare process performance. The following examples show the fundamental principles, scope of application, and versality of control chart as a statistical process control and data analysis tool.

4.1 Ambulance Response Time

4.1.1 Introduction

In 2016, the National Health Service (NHS), a government funded health care and medical services in England, realised that the ambulance services are experiencing difficulties to reach patients with life-threatening condition or critically ill and injured patients quickly enough as the service system struggles to cope with rising demand for emergencies service. There are 11 NHS Ambulance Trust providing emergency medical services in England, the call handlers will handle the emergency 999 calls to ascertain or identify the urgency of the calls and assign ambulance resources appropriately (NHS England, 2019a). Historically, ambulance response target requires the call handlers to assess and identify patients' condition and location within 1 minute (60 seconds), from receiving call to sending an ambulance crew or vehicle to the scene (NHS England, 2017a). If the call is immediately life-threatening or an emergency, the ambulance should be reached in average time of 8 minutes (NHS England, 2017a). However, the NHS England found out that 1 minute target was the main leading cause of inefficiencies in the ambulance service system as the if call handlers were not able to accurately assess the patient's emergency condition at the end of 1 minute of receiving call, but due to accident & emergency departments (A&E) have to achieve the targets of responding to patients within 8 minutes, ambulance crews had no choice but to be dispatched within timeframe (National Health Executive, 2017). Sometimes, multiple vehicles (e.g., three or four vehicles) may be sent to the same 999 call in order to meet the 8-minute target and meaning that some crews were stood down before they reached the patient's location (NHS England, 2017a) In addition, precious time and resource will be wasted as the ambulances will be recalled when it is determined that the patient is not in urgent need of immediate medical attention.

To ensure the most serious cases are prioritized, the sickest patients receive the quickest paramedic response and all patients receive the proper response, NHS England introduced a new set of ambulance standards across the country in July 2017 (NHS England, 2017b). The new restructured system is a triage system, calls are triaged into four categories based on the severity patient's condition and the need of immediate medical response (North East Ambulance Service, 2017). For life-threatening illness or injuries incidents, such as respiratory or cardiac arrest, which need the immediate response are designated as Category 1, ambulance and paramedics are now needed to reach patient in an average time of 7 minutes. For emergency calls or any potentially serious conditions, such as chest pain and stroke, are designated as Category 2. For calls that urgent but are not immediately life-threatening (e.g., uncomplicated diabetics or pain control) and calls that are non-urgent (e.g. stable clinical cases) are designated as Category 3 and 4 respectively.

Call handlers are given a new set of pre-triage questions with more time on call to allocate the incidents into one of the response categories and to identify those patients in need of the quickest medical attention as fast and accurate as possible (NHS England, 2019b). Then, the most appropriate vehicle will be dispatched to each patient that meets their medical need within a timeframe. Rather than sending several vehicles to one call, new system now is sending one vehicle and providing the patient the right and appropriate medical response. This will free ambulance and paramedics up to attend other calls. In addition, a set of new clinical prioritisation codes are introduced to better describe the patient's condition and following response requirement. The new system updated a decades old system and the new standard was gradually rolled out across the country, and by April 2018 all ambulance trusts in England completed the transition to the new response performance standards and had the ability to report on new systems indicator (Nuffield Trust, 2019). A control chart will be used monitor the ambulance response time and to analyse whether the implementation of new system has improved the process.

4.1.2 Methods

The existing data of ambulance average response time for Category 1 of NHS England over a period from August 2017 to May 2019 are extracted from NHS database on 20 June 2018 using Microsoft Excel 2016. NHS England has collected, compiled and summarized the data from all the eleven ambulance trusts in England, and then

published the data on new ambulance system indicator monthly since August 2017. The count of incidents and total response hours (from receiving the 999 call to the vehicle reaching at patient's location) were determined on a monthly basis, average response time is derived by dividing the count of incidents by total response hours and all data will be analysed using Minitab 18. XmR Chart (based normal distribution) was selected for monitoring average mean of ambulance response time and to analyse whether implementation of new system has improved the process. The procedures to construct XmR chart included:

Step 1: Identify dataset

(i) Calculate the mean response time (in Minute),

$$X = \frac{total\ response\ time\ (in\ hour)}{count\ of\ incidents} x60\ .$$

Table 4.1: Data of Ambulance Response Time for Category 1 Call

Sample Number	**Month/Year**	**Count of Incidents**	**Total Response Time (Hour)**	**Average response time (Min), *X***	**MR**
Before Implementation of New System					
1	August/2017	10,233	1,575.3444	9.2368	
2	September/2017	25,533	3,453.3231	8.1150	1.1219
3	October/2017	27,768	3,662.1444	7.9130	0.2019
4	November/2017	50,380	6,679.3322	7.9547	0.0417
5	December/2017	63,476	9,379.4667	8.8658	0.9111
6	January/2018	60,170	8,343.0103	8.3194	0.5464
7	February/2018	52,766	7,284.1356	8.2828	0.0367
8	March/2018	58,932	8,423.2367	8.5759	0.2931
SUM		349,258	48,799.9933	67.2635	3.1529
Mean		-	-	8.4080	0.4504
After Implementation of New System					
9	April/2018	54,279	6,893.5639	7.6201	0.9557

10	May/2018	58,154	7,490.9328	7.7287	0.1086
11	June/2018	56,481	7,150.9114	7.5964	0.1323
12	July/2018	58,884	7,333.2239	7.4722	0.1242
13	August/2018	53,240	6,332.1078	7.1361	0.3361
14	September/2018	52,568	6,299.7981	7.1905	0.0543
15	October/2018	55,383	6,631.7800	7.1846	0.0058
16	November/2018	56,484	6,756.8031	7.1774	0.0072
17	December/2018	60,238	7,131.8356	7.1037	0.0737
18	January/2019	60,108	7,138.7222	7.1259	0.0222
19	February/2019	54,648	6,634.5533	7.2843	0.1584
20	March/2019	59,560	6,943.0322	6.9943	0.2900
21	April/2019	56,911	6,625.6161	6.9852	0.0091
22	May/2019	57,751	6,641.8931	6.9005	0.0847
SUM		794,689	96,004.7733	101.5001	2.3625
Mean		-	-	7.2500	0.1082

Step 2: Determining the baseline parameters (Data before Implementation of New System)

To set up the MR chart:

(i) Compute the moving range (MR); which is absolute value of the differences between the successive values such as $MR_i = |X_i - X_{i-1}|$.

(ii) Compute the value of centre line (CL), the upper control limit (UCL) and lower control limit (LCL).

Table 4.2: CL, UCL and LCL for MR chart of average of ambulance response time allocated in Category 1 call (Before Implementation of New System)

	CL, $\overline{MR}$	***UCL***	***LCL***
Formula	$\frac{\sum_{i=2}^{n} MR_i}{n-1}$	$D_4 \; x \; \overline{MR}$ $= 3.627 \; x \; \overline{MR}$	$D_3 \; x \; \overline{MR}$ $= 0 \; x \; \overline{MR}$
Before Implementation (August/2017-March/2018)	$\frac{\sum_{i=2}^{8} MR_i}{8-1}$ $= \frac{3.1529}{7}$ $= 0.4504$	$3.267 \; x \; 0.4504$ $= 1.4715$	$0 \; x \; \overline{MR} = 0$

(iii) Plot the MR_i, CL, UCL and LCL values on the same graph, and put the graph below of X chart. (Figure 4.1 to Figure 4.4 plots the control chart constructed by Minitab).

<u>To set up the X chart:</u>

(i) Compute the value of centre line (CL), the lower control limit (LCL) and upper control limit (UCL).

Table 4.3: CL, UCL and LCL for X chart of average of ambulance response time allocated in Category 1 call (Before Implementation of New System)

	CL, $\bar{X}$	***UCL***	***LCL***
Formula	$\frac{\sum_{i=1}^{n} X_i}{n}$	$\bar{X} + 2.66 \; x \; \overline{MR}$	$\bar{X} - 2.66 \; x \; \overline{MR}$
Before Implementation (August/2017-March/2018)	$\frac{\sum_{i=1}^{8} X_i}{8}$ $= \frac{67.2635}{8}$ $= 8.4080$	$8.4080 + 2.66 \; x \; 0.4504$ $= 9.6060$	$8.4080 - 2.66 \; x \; 0.4504$ $= 7.2099$

(ii) Plot the X_i, CL, UCL and LCL values on the same graph, and put the graph above of MR chart. (Figure 4.1 to Figure 4.4 plots the control chart constructed by Minitab).

4.1.3 Data Discussion

Between August 2017 to March 2018 (before the implementation of new ambulance system), there were total 349,258 incidents and the total ambulance response times for this 8-month period were 48,800 hours. Monthly average was around 8.408 minute. The XmR control chart with the center line at $\bar{X}$=8.408 and the upper and lower control limit are shown in Figure 4.1. The average of ambulance response time for each month is plotted on the upper chart (X chart/Individual Chart) and the moving range for each month is plotted on the below chart (Moving Range chart) in Figure 4.1. There is no sign that the process is out of control, so these limits can be adopted to test whether a process change has improved the stable process (Phase II analysis).

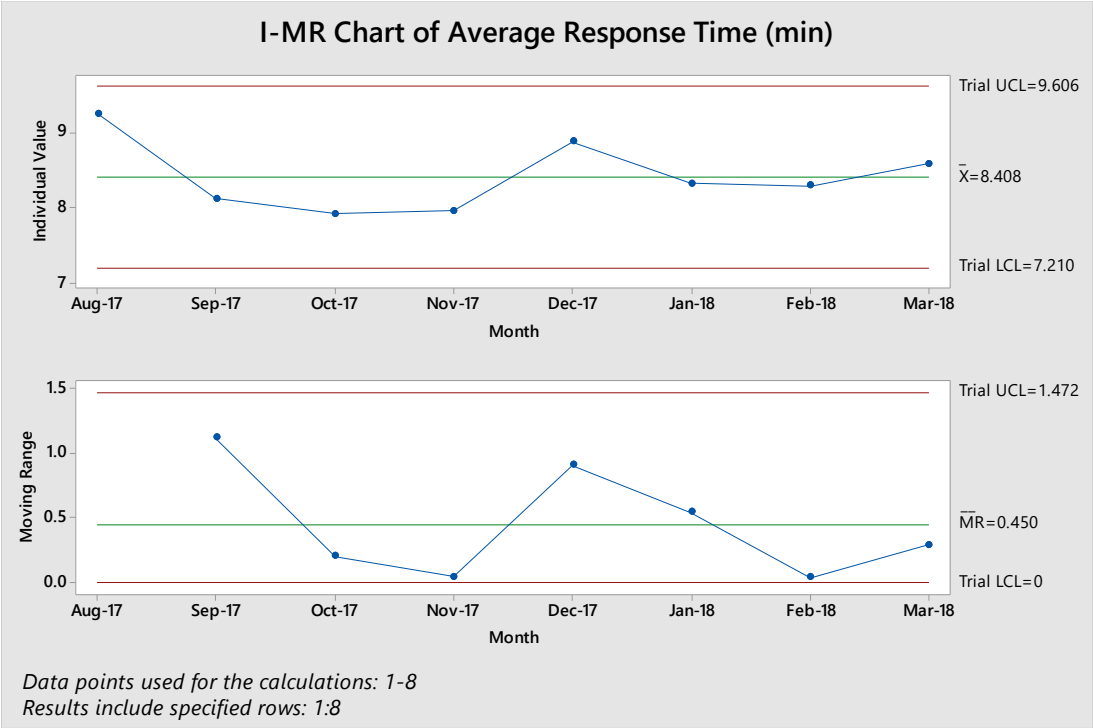

Figure 4.1: XmR Chart for the data before implementation of new system in Table 4.1.

Table 4.1 contains data on average ambulance response time after the new system implementation, from April 2018 to May 2019 (sample 9 to 22). These data are plotted in Figure 4.2 on the continuation of the XmR chart developed in Figure 4.1.

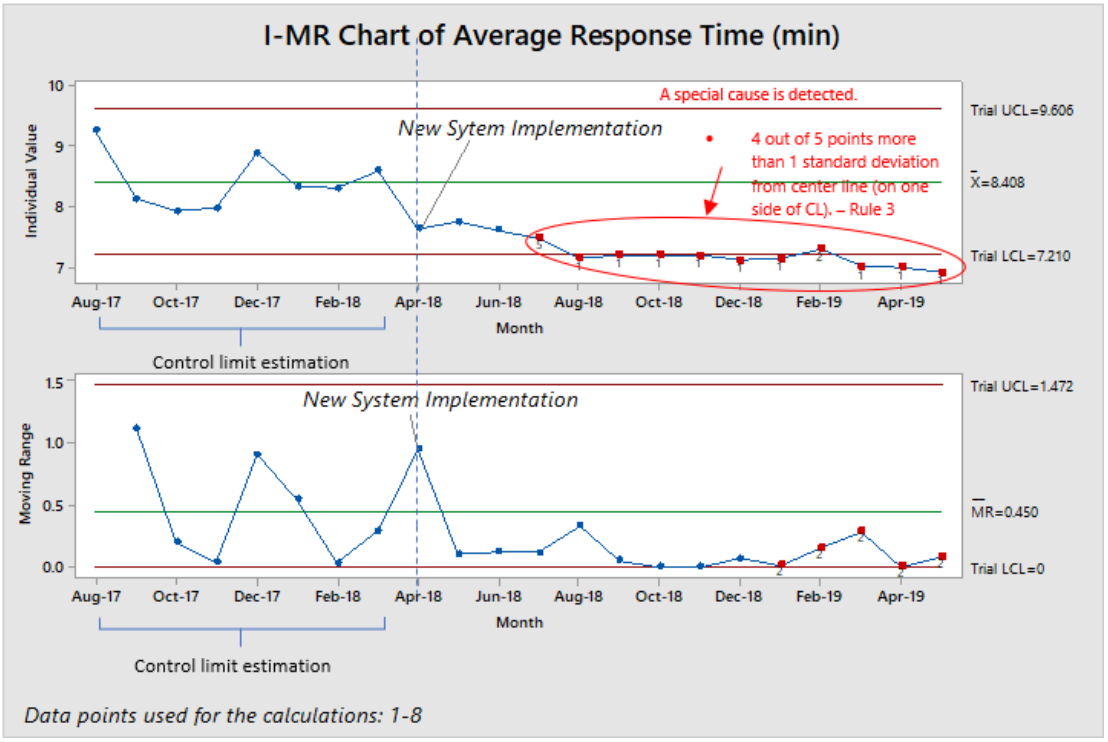

Figure 4.2: Continuation of the XmR chart in Figure 4.1.

A change or intervention in an improvement plan are deliberate attempts to introduce special cause of variations. From inspection of Figure 4.2, a special cause due to Rule 3 is detected, which probably a sign that the process might has measurably shifted. It showed that the process after the new system implementation is now operating at a new response time level that is significantly better than the trial center line level of $\bar{X}$=8.408. Thus, it is logical to recalculate the new control limits based on the new data (after the implementation of new ambulance system). The new control limits are calculated as Table 4.4 and Table 4.5.

Table 4.4: New CL, UCL and LCL for MR chart of average of ambulance response time allocated in Category 1 call (After Implementation of New System)

	CL, $\overline{MR}$	***UCL***	***LCL***
Formula	$\frac{\sum_{i=2}^{n} MR_i}{n-1}$	$D_4 \; x \; \overline{MR}$ $= 3.627 \; x \; \overline{MR}$	$D_3 \; x \; \overline{MR}$ $= 0 \; x \; \overline{MR}$
After Implementation	$\frac{\sum_{i=9}^{22} MR_i}{14-1}$ $= \frac{1.4068}{13}$ $= 0.1082$	$3.267 \; x \; 0.1082$ $= 0.3535$	$0 \; x \; \overline{MR} = 0$

Table 4.5: New CL, UCL and LCL for X chart of average of ambulance response time allocated in Category 1 call (After Implementation of New System)

	CL, $\bar{X}$	***UCL***	***LCL***
Formula	$\frac{\sum_{i=1}^{n} X_i}{n}$	$\bar{X} + 2.66 \; x \; \overline{MR}$	$\bar{X} - 2.66 \; x \; \overline{MR}$
After Implementation	$\frac{\sum_{i=9}^{22} X_i}{14}$ $= \frac{101.5001}{14}$ $= 7.2500$	$7.2500 + 2.66 \; x \; 0.1082$ $= 7.5378$	$7.2500 - 2.66 \; x \; 0.1082$ $= 6.9622$

A hypothesis test also can be conducted to test the hypothesis that the process average response time in this new system implementation differ from the process average response time before implementation. The hypotheses are

$$H_0: \mu = 8.408$$

$$H_1: \mu < 8.408$$

The average response time after the new system implementation can be estimate by $\bar{X}_1$ $= \frac{\sum_{i=9}^{22} X_i}{14} = \frac{101.5001}{14} = 7.2500$ and the standard deviation are $s = \sqrt{\frac{\sum_{i=9}^{22} {X_i}^2 - \frac{\left(\sum_{i=9}^{22} X_i\right)^2}{14}}{14-1}} = \sqrt{\frac{736.7336 - \frac{101.5001^2}{14}}{14-1}} = 0.2568.$

The test statistic for the above hypotheses is

$$t_0 = \frac{\bar{x}_1 - 8.408}{s/\sqrt{n}} = \frac{7.2500 \ - 8.408}{0.2568/\sqrt{14}} = -16.8724$$

We reject H_0 if $t_0 < t_{0.05,n-1}$. Since the calculated of test statistic is less than $-t_{0.05,13} = -2.16$, we reject H_0 and conclude that there has been substantial decrease in the average ambulance response time. Both SPC chart and hypothesis test can help to distinguish whether the process patterns exhibit common or special cause of variation. However, SPC chart present in the form of a graph, provide easier and often faster way to detect this change. Since the process have shifted, the control limit will be revised based on the data after new system implementation, from April 018 to April 2019 (Sample 9 to 22). The revised control limits for X chart are CL =$\bar{X}$=7.2500, UCL = 7.5378 and LCL = 6.9622 and for MR chart are CL = $\overline{MR}$ = 0.1082, UCL = 0.3535 and LCL = 0 (Table 4.5). Figure 4.3 illustrate the XmR chart with these revised parameters. From inspection of Figure 4.3, there are 4 points above the upper control limit and 2 points below the lower control limit for X chart (Rule 1 and Rule 2).

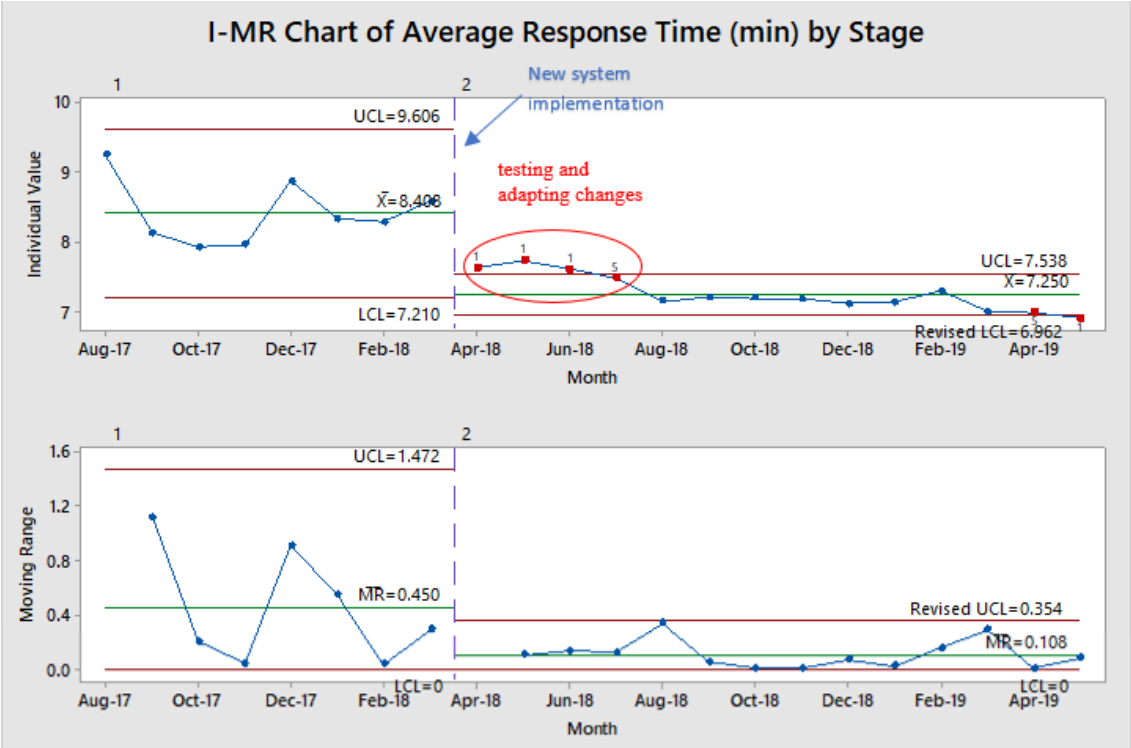

Figure 4.3: Revised control limits on the average ambulance response time XmR control chart

Investigation of the first 4 months (April 2018 to July 2018) data indicates that the new system has updated a decades old system. Thus, data during this period is still

in the middle of adapting changes after the new system implementation. Therefore, it seems reasonable to eliminate these 4 months data, the new center line and revised control limits are calculated as

Table 4.6: CL, UCL and LCL for XmR chart of average of ambulance response time (exclude 4 out-of-signal data points)

For MR Chart:	For X Chart:
New CL, $\overline{MR} = \frac{\sum_{i=14}^{22} MR_i}{10-1} = \frac{0.7056}{9} =$ 0.0784	New CL, $\bar{X} = \frac{\sum_{i=13}^{22} X_i}{10} = \frac{71.0826}{10} = 7.1083$
New UCL = $D_4 \; x \; \overline{MR}$ $= 3.627 \; x \; \overline{MR}$ = 0.2561	New UCL = $\bar{X} + 2.66 \; x \; \overline{MR}$ $= 7.1083 + 2.66 \; x \; 0.0784$ = 7.3168
New LCL = $D_3 \; x \; \overline{MR}$ $= 0 \; x \; \overline{MR}$ = 0	New LCL = $\bar{X} - 2.66 \; x \; \overline{MR}$ $= 7.1083 - 2.66 \; x \; 0.0784$ = 6.8998

Figure 4.4 illustrate the XmR chart with these new parameters. From examination of Figure 4.4, all the points fall inside the new control limit; thus, the process is in state of control at this new level. The new system seeks all ambulance trusts respond in average time of 7 minutes; the control charts show that there is a notable improvement in reducing the average response time soon after the new system is implemented, from $\bar{X}$ = 8.408 to $\bar{X}$ = 7.1083. In spite of the improvement in response time following the system changes in process, the process means $\bar{X}$ = 7.1083 is still high if compare with 7 minutes target. However, Table 4.1 and XmR chart in Figure 4.4 show that the average ambulance response time standards of 7 minutes was first met during the period of March to May 2019 (sample 20 to 22). Thus, control chart should be used to monitor the sustainability of continuous improvements in process by detecting any future special cause variation of an increase in average of ambulance response time.

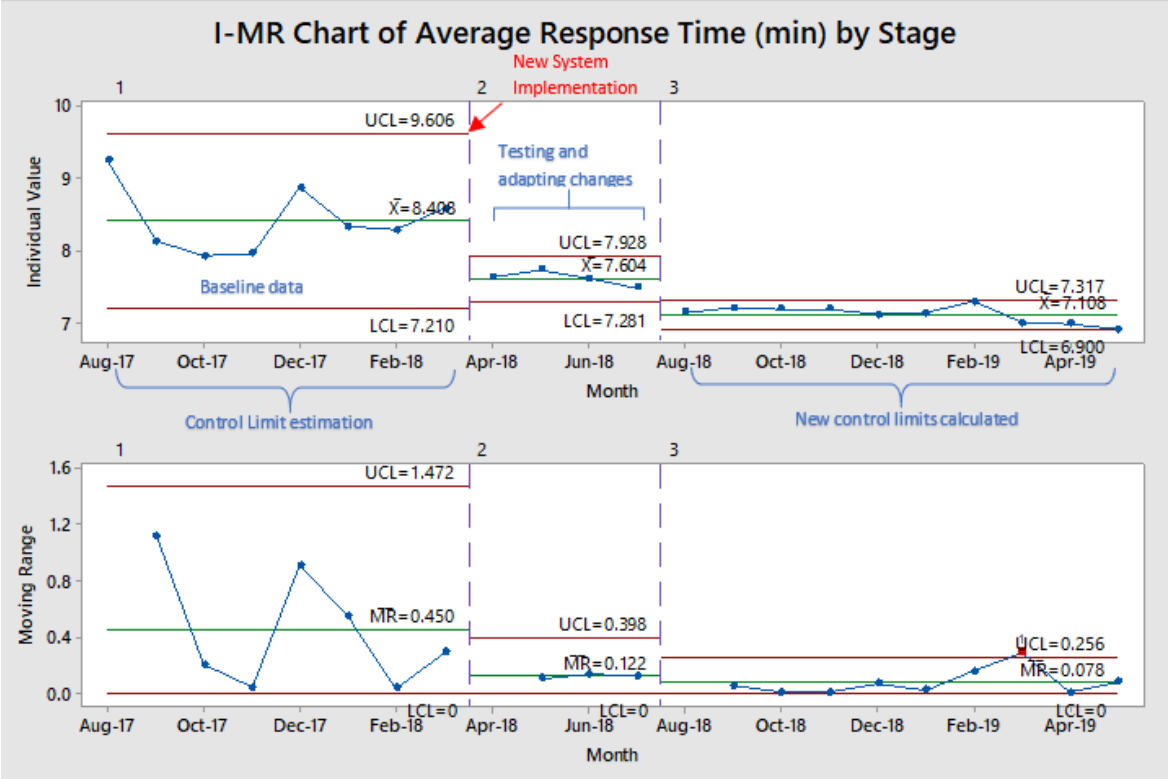

Figure 4.4: New control limits on the average ambulance response time XmR control chart

4.2 Medical Device/Equipment Adverse Events

4.2.1 Introduction

Medical devices and equipment play a crucial role in the diagnosis, treatment and management of medical conditions in home, in hospital and in surgery, and are the trading tools for healthcare professionals (Ward and Clarkson, 2004; Davenport, 2019). They range from simple, low risk devices such as disposable gloves and thermometer to complex, high risk devices such as implantable pacemakers, defibrillators and breast implants that used to support and sustain life. Medical devices are classified into three categories, which are Class I (devices which present minimal or lowest risk, such as dental floss, tongue depressors and elastic bandages), Class II (medium risk devices such as wheelchairs, endoscopes and ultrasound devices), and Class III (high risk devices used to sustain life such as implantable pacemakers and defibrillators). Medical devices and equipment are used in increasing number over the year and demand for complex and innovative products are continue rising in global market (Axenics, 2017). It is unavoidably a risk that failure or unavailability of these devices and equipment; or failure of associated procedure might lead to injury, threats to life

or death. One of the medical device adverse events that bring global concern was the case with the defective breast implant scandal, which manufactured by French company Poly Implant Prothese (PIP) (Russell, 2019). The implants have been discovered to contain unapproved silicone which designed for industrial use and the news of investigation into this case was widely reported in the media in December 2011(NHS Choices, 2012). The scandal affected around 300,000 women all over the world such as France, England, South Africa and so on.

Following the serious case with defective breast implants, the UK government has launched a rapid inquiry into the safety of medical devices. In May 2012, the Department of Health issued a report to improve the safety of patients, which include the below recommendations (MHRA, 2014):

(i) Maximise adverse medical device incidents reports and ensure that reports are high quality for learning from the events that do occur;

(ii) All parties (healthcare practitioners, professionals, patients and industry) must participate as equal partners in the alert system with the sole purpose of reducing the medical device adverse events;

(iii) The Medicine and Healthcare products Regulatory Agency (MHRA), should evaluate its activities continuously to make certain that everything it does is consistent with this purpose and to promotes this shared purpose among all those partners that involved in medical device alert.

In April 2014, NHS England and MHRA have formed a partnership to announce a new system to assist hospital to increase incident reporting for medical devices and quality of data, to improve learning in medical device safety and to guide practice to reduce harm from medical device events (MHRA, 2014), system must implemented by 19th September 2014. This partnership includes several initiatives as follow:

(i) Developed a new integrated National Learning and Reporting System (NRLS) to share the medical device adverse events data between NHS and MHRA.

(ii) Established a National Medical Devices Safety Improvement Network as a new forum for reviewing the recognised and potential safety matters, analysing on adverse events trends and patterns; and identifying measurements to improve the safety of medical devices.

(iii) Improve feedback system from NRLS and the MHRA to maximize learning at national level.

The Medicine and Healthcare products Regulatory Agency (MHRA) is a government agency in UK that responsible to ensure the medicines and medical devices or equipment function properly and are adequately safe (Stephenson, 2014). Clinical consultants and medical device specialist will assess the risk and determine the triage of all submitted medical device adverse events. The medical device adverse events can be failure or unavailability of the devices or equipment, user error, wrong device used or any other cases which medical devices is suspected as a contributing cause of the adverse events. The process from receive a report to determine the triage takes between three to five days, and the triage determination will let MHRA to concentrate on the issues that pose the highest risk to the safety of patient, and where their intervention will assist to resolve the problem. Not only are risks assessed and evaluated as part of this process, but investigations are supported by organization for identifying and analysing on emerging incident trends and patterns (MHRA, 2014). After the investigation and risk assessment done, MHRA will issue a warning or alert if necessary. There are two types of warning about medical devices which are (1) field safety notice – manufacturer matters, recall a medical device or equipment due to clinical or technical reasons; (2) medical device alerts – provide info about medical device recalls and suggest what appropriate action and measures should be taken by NHS hospitals(Thompson , et al., 2011). The entire process ensures that each incident report not only help MHRA to learn the medical device and its use, but also take appropriate steps to prevent similar problems from recurring. SPC chart can be used to monitor the number of the medical device adverse events and to analyse whether NHS and MHRA has successfully reduce the number of adverse events.

4.2.2 Methods

All reported medical device or equipment adverse events happening in England between 1 January 2009 to 30 September 2018 were extracted from the NRLS database on 27 June 2019 using Excel 2016 and Minitab 18. NRLS has compiled and summarized the data submitted by all NHS organizations, patients, practitioners, nurse and staff, and then published the National Patient Safety Incident Reports quarterly. All reported medical device adverse events will be reviewed and analysed using Minitab 18. Since the sample size are not constant, U chart (based on the Poisson

Distribution) was selected for monitoring rate of devices adverse events per incident. The procedures to construct U chart included:

Step 1: Identify dataset

(i) Calculate the rate of medical device adverse events per incident U_i in each subgroup

$$U_i = \frac{C_i}{n_i}$$

Table 4.7: Data for the Number of Medical Device Adverse Event and Incidents of NRLS.

Sample Number, i	**Month/Year**	**Number of Medical Devices Adverse Events, C_i**	**Number of Incidents, n_i**	**Rate of Medical Devices Adverse Events per incident, $U_i = \frac{C_i}{n_i}$**
Before recommendation from Department of Health				
1	Jan 2009 - Mar 2009	7,765	263,343	0.029486
2	Apr 2009 - Jun 2009	8,930	281,660	0.031705
3	Jul 2009- Sep 2009	8,408	274,040	0.030682
4	Oct 2009 - Dec 2009	8,349	274,300	0.030437
5	Jan 2010 - Mar 2010	8,725	292,044	0.029876
6	Apr 2010 - Jun 2010	9,050	296,258	0.030548
7	Jul 2010 - Sep 2010	8,953	307,399	0.029125
8	Oct 2010 - Dec 2010	9,157	312,140	0.029336
9	Jan 2011 - Mar 2011	9,559	317,948	0.030065
10	Apr 2011 - Jun 2011	9,969	329,843	0.030223
11	Jul 2011- Sep 2011	9,980	335,972	0.029705
12	Oct 2011 - Dec 2011	10,655	336,790	0.031637
13	Jan 2012 - Mar 2012	10,624	355,482	0.029886
14	Apr 2012 - Jun 2012	10,388	350,881	0.029605

		130,512	4,328,100	$\bar{U} = \frac{\sum_{i=1}^{14} C_i}{\sum_{i=1}^{14} n_i} = \mathbf{0.030155}$
After recommendation from Department of Health				
15	Jul 2012 - Sep 2012	9,799	352,663	0.027786
16	Oct 2012 - Dec 2012	10,627	369,182	0.028785
17	Jan 2013 - Mar 2013	10,413	382,496	0.027224
18	Apr 2013 - Jun 2013	10,953	388,969	0.028159
19	Jul 2013 - Sep 2013	10,868	391,992	0.027725
20	Oct 2013 - Dec 2013	11,290	402,393	0.028057
21	Jan 2014 - Mar 2014	11,550	410,628	0.028128
22	Apr 2014 - Jun 2014	12,020	426,547	0.028180
23	Jul 2014 - Sep 2014	11,477	433,038	0.026503
		98,997	3,557,908	$\bar{U} = \frac{\sum_{i=15}^{23} C_i}{\sum_{i=15}^{23} n_i} = \mathbf{0.027824}$
After NHS and MHRA partnership				
24	Oct 2014 - Dec 2014	12,252	447,730	0.027365
25	Jan 2015 - Mar 2015	12,057	445,612	0.027057
26	Apr 2015 - Jun 2015	12,844	458,389	0.028020
27	Jul 2015 - Sep 2015	12,632	456,879	0.027648
28	Oct 2015 - Dec 2015	13,051	470,620	0.027732
29	Jan 2016 - Mar 2016	13,285	485,585	0.027359
30	Apr 2016 - Jun 2016	13,828	492,567	0.028073
31	Jul 2016 - Sep 2016	13,001	494,376	0.026298
32	Oct 2016 - Dec 2016	12,759	497,922	0.025624
33	Jan 2017 - Mar 2017	13,317	505,035	0.026368
34	Apr 2017 - Jun 2017	13,328	506,818	0.026297
35	Jul 2017 - Sep 2017	13,463	520,971	0.025842
36	Oct 2017 - Dec 2017	13,344	526,561	0.025342
37	Jan 2018 - Mar 2018	13,580	537,875	0.025248
38	Apr 2018 - Jun 2018	13,716	533,408	0.025714

39	Jul 2018 - Sep 2018	13,138	517,438	0.025390
		209,595	7,897,786	$\bar{U} = \frac{\sum_{i=24}^{39} C_i}{\sum_{i=24}^{39} n_i} = 0.026538$

Step 2: Determining the baseline parameters (Data before recommendation from Department of Health)

(i) Compute the value of centre line (CL), the upper control limit (UCL) and lower control limit (LCL).

Table 4.8: CL, UCL and LCL for U chart of average rate of medical device adverse events per incident (Before recommendation from Department of Health)

Sample Number, i	**Month/Year**	**Number of Incidents, n_i**	$CL = \bar{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \bar{U} + 3\sqrt{\frac{\bar{U}}{n_i}}$	$LCL = \bar{U} - 3\sqrt{\frac{\bar{U}}{n_i}}$
Before recommendation from Department of Health					
1	Jan 2009 - Mar 2009	263,343	$CL = \bar{U} = \frac{\sum_{i=1}^{14} C_i}{\sum_{i=1}^{14} n_i} = \frac{130,512}{4,328,100} = 0.030155$	0.031170	0.029139
2	Apr 2009 - Jun 2009	281,660		0.031136	0.029173
3	Jul 2009- Sep 2009	274,040		0.031150	0.029159
4	Oct 2009 - Dec 2009	274,300		0.031149	0.029160
5	Jan 2010 - Mar 2010	292,044		0.031119	0.029191
6	Apr 2010 - Jun 2010	296,258		0.031112	0.029197
7	Jul 2010 - Sep 2010	307,399		0.031094	0.029215

8	Oct 2010 - Dec 2010	312,140		0.031087	0.029222
9	Jan 2011 - Mar 2011	317,948		0.031078	0.029231
10	Apr 2011 - Jun 2011	329,843		0.031062	0.029247
11	Jul 2011- Sep 2011	335,972		0.031053	0.029256
12	Oct 2011 - Dec 2011	336,790		0.031052	0.029257
13	Jan 2012 - Mar 2012	355,482		0.031028	0.029281
14	Apr 2012 - Jun 2012	350,881		0.031034	0.029275

(ii) Plot the U_i, CL, LCL and UCL values on the same graph (Figure 4.5 to Figure 4.11 plots the control chart constructed by Minitab).

4.2.3 Data Discussion

Between January 2009 to June 2012 (before the Department of Health issue the report with recommendation), there were total 130,512 medical device adverse events and the total incident for this period were 4,328,100 (sample 1 to 14). The average rate of medical device adverse events per incident was around 0.030155. The U control chart with the center line at $\overline{U}$=0.030155 and the upper and lower control limit are shown in Figure 4.5 (sample 1 to 14). Three points plot outside the control limits, sample 2(Apr 2009 - Jun 2009), 7(Jul 2010 - Sep 2010) and 13(Jan 2012 - Mar 2012); thus, the process is not in control. These points must be examined to check whether a special cause can be determined.

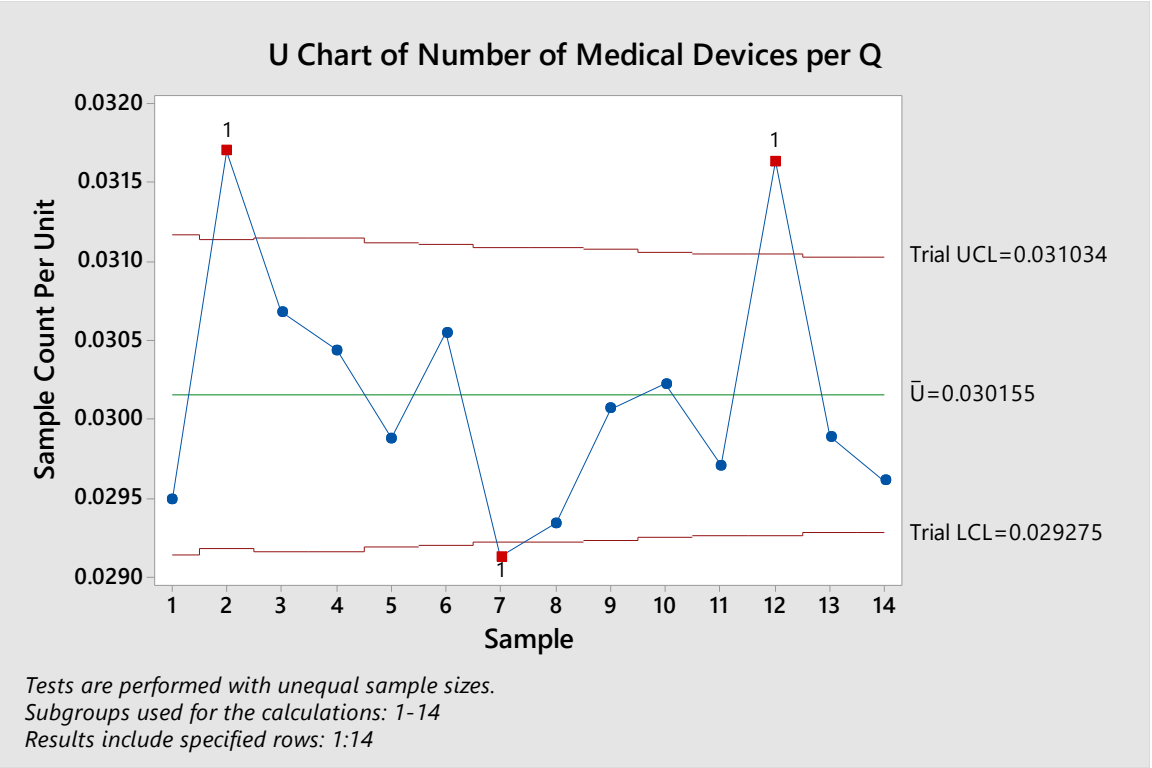

Figure 4.5: U chart for the data before recommendation from Department of Health in Table 4.8.

Analysis of the data from sample 2, period from April 2009 to June 2009, reveals that there are four medical device alert issues during this period. Alert issues due to premature failure of bioprosthetic heart valves as a result of valves are not properly washed or cleaned before implantation, damage to tonometer prism which caused by inappropriate use of disinfectants, difficulty releasing the suprarenal stent-graft during deployment and unexpected failure of implantable pacemakers. Furthermore, the unusually high average rate of medical device adverse events per incident in sample 12 resulted from the defective PIP breast implant, rapid battery depletion of implantable cardioverter defibrillators and failure of stapler loading units in thoracic surgery. The subsequent action has been for recommended by MHRA for these two points to prevent similar incident from happening. In addition, there is no special cause for the out-of-control signal from sample 7 can be determined; thus, this sample will be retained. Therefore, sample 2 and 12 are eliminated, and the new revised control limits are calculated as:

$$\text{CL} = \bar{U} = \frac{\sum_{i=1}^{1} C_i + \sum_{i=3}^{11} C_i + \sum_{i=13}^{14} C_i}{\sum_{i=1}^{1} n_i + \sum_{i=3}^{11} n_i + \sum_{i=13}^{14} n_i} = \frac{110{,}927}{3{,}709{,}650} = 0.029902$$

Table 4.9: Revised CL and Control limits for U chart

Sample Number, i	**Month/Year**	**Number of Incidents, n_i**	$CL = \overline{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \overline{U} + 3\sqrt{\frac{\overline{U}}{n_i}}$	$UCL = \overline{U} - 3\sqrt{\frac{\overline{U}}{n_i}}$
Before recommendation from Department of Health					
1	Jan 2009 - Mar 2009	263,343	$CL = \overline{U} = 0.029902$	0.030913	0.028891
2	Apr 2009 - Jun 2009	281,660		0.030880	0.028925
3	Jul 2009- Sep 2009	274,040		0.030893	0.028911
4	Oct 2009 - Dec 2009	274,300		0.030893	0.028912
5	Jan 2010 - Mar 2010	292,044		0.030862	0.028942
6	Apr 2010 - Jun 2010	296,258		0.030855	0.028949
7	Jul 2010 - Sep 2010	307,399		0.030838	0.028967
8	Oct 2010 - Dec 2010	312,140		0.030831	0.028974
9	Jan 2011 - Mar 2011	317,948		0.030822	0.028982
10	Apr 2011 - Jun 2011	329,843		0.030806	0.028999
11	Jul 2011- Sep 2011	335,972		0.030797	0.029007
12	Oct 2011 - Dec 2011	336,790		0.030796	0.029008
13	Jan 2012 - Mar 2012	355,482		0.030772	0.029032

14	Apr 2012 - Jun 2012	350,881		0.030778	0.029027

The revised CL and control limits are shown on the control chart in Figure 4.6. The sample 2 and 12 are not dropped from the control chart, but they have been excluded from calculations of control limits. Note also the average rate of medical device adverse events per incident from sample 7 are fall inside the revised control limits, the process is in control. The new control limits in Table 4.9 and Figure 4.6 can be used for monitoring the further data (sample 15 to 23) in Table 4.7 and to test whether the first process change (Recommendation from Department of Health) has impact in reducing the rate of medical device adverse events (Phase II analysis).

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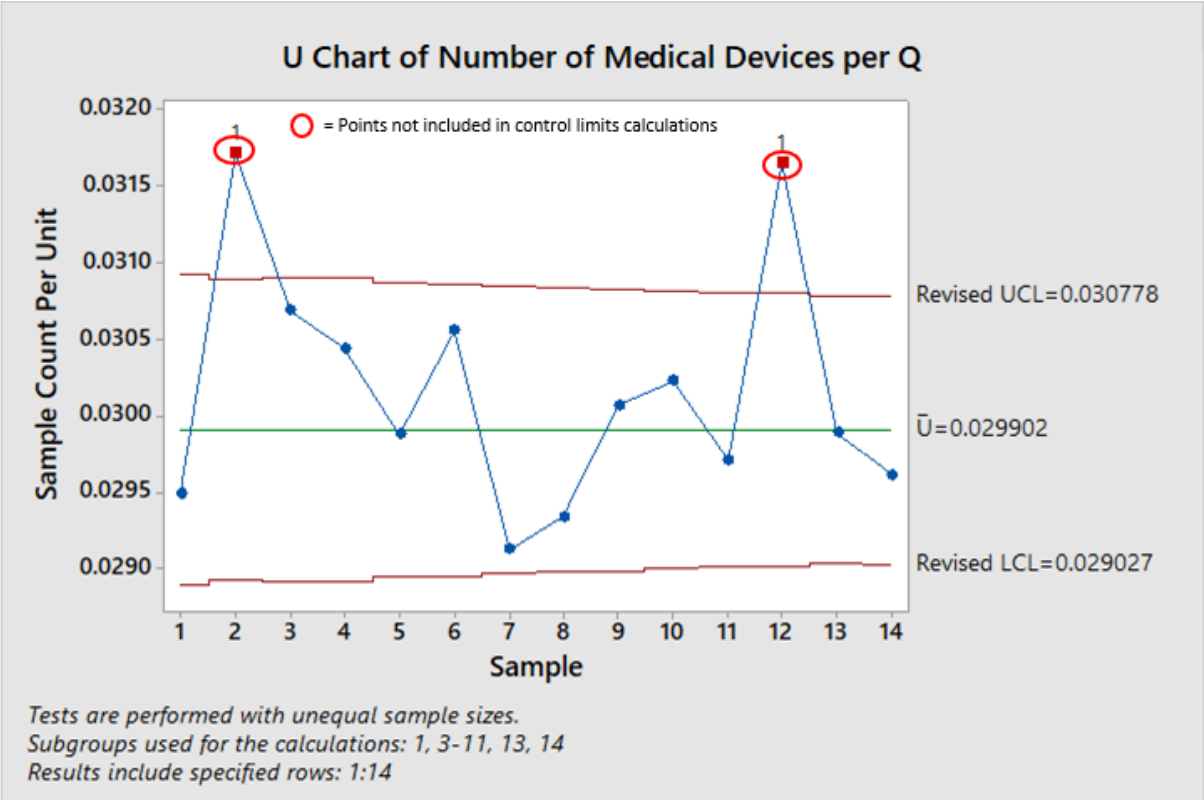

Figure 4.6: Revised CL and control limits for the data in Table 4.9.

Table 4.7 contains control limits on average rate of medical device adverse events per incident after the recommendation from Department of Health, before NHS and MHRA form partnership, from July 2012 to September 2014 (sample 15 to 23). These data are plotted in Figure 4.7 on the continuation of the U chart developed in Figure 4.6.

Table 4.10: Continuation of data from July 2012 to September 2014 by using $\bar{U} = 0.029902$ which get from Table 4.9.

Sample Number, i	**Month/Year**	**Number of Incidents, n_i**	$CL = \bar{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \bar{U} + 3\sqrt{\frac{\bar{U}}{n_i}}$	$UCL = \bar{U} - 3\sqrt{\frac{\bar{U}}{n_i}}$
After recommendation from Department of Health					
15	Jul 2012 - Sep 2012	352,663	$CL = \bar{U} = 0.029902$	0.030776	0.029029
16	Oct 2012 - Dec 2012	369,182		0.030756	0.029048
17	Jan 2013 - Mar 2013	382,496		0.030741	0.029063
18	Apr 2013 - Jun 2013	388,969		0.030734	0.029070
19	Jul 2013 - Sep 2013	391,992		0.030731	0.029074
20	Oct 2013 - Dec 2013	402,393		0.030720	0.029084
21	Jan 2014 - Mar 2014	410,628		0.030712	0.029093
22	Apr 2014 - Jun 2014	426,547		0.030697	0.029108
23	Jul 2014 - Sep 2014	433,038		0.030691	0.029114

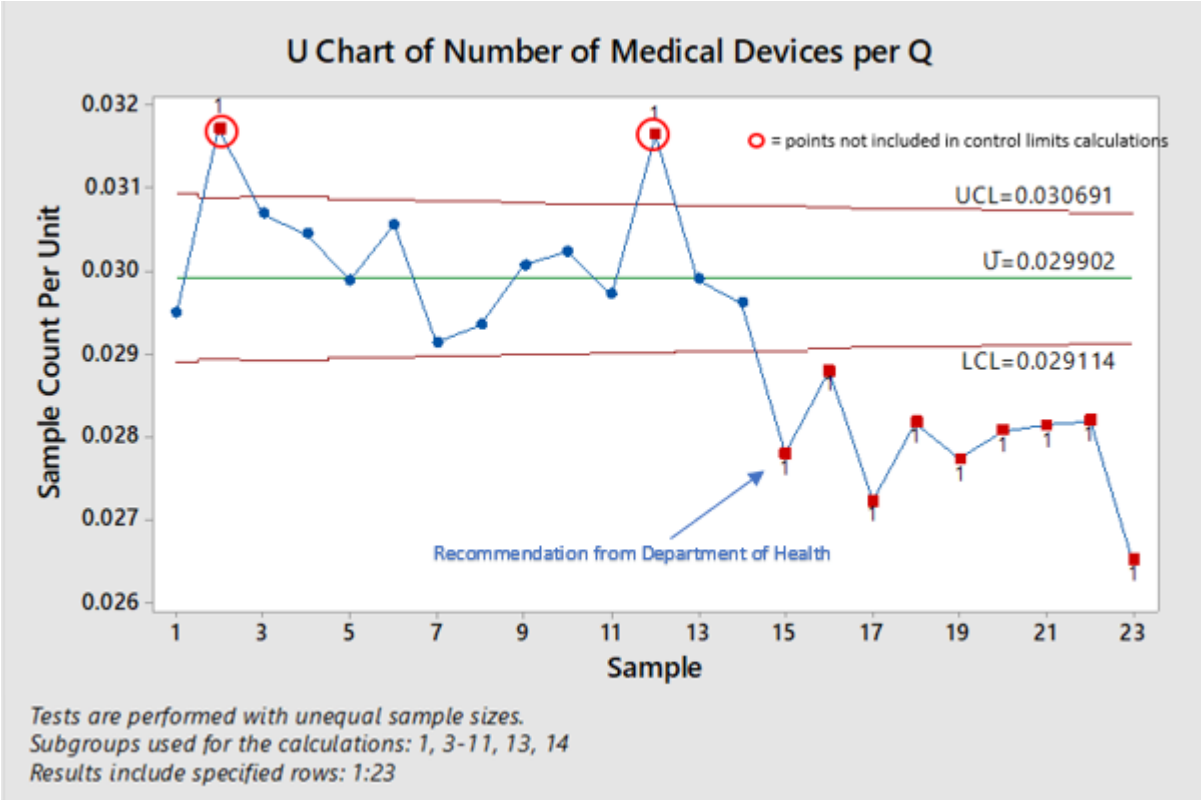

Figure 4.7. Continuation of U chart in Figure 4.6.

Figure 4.7 indicates the data point from July 2012 to September 2014 (sample 15 to 23) fall below the revised lower control limit, the process is not in control. From inspection of figure 4.7, a special cause is detected, which probably a sign that the process might has measurably shifted. It showed that the process after the recommendation from Department of Health is now operating at a new level that is significantly better than the trial center line level of $\bar{U}$= 0.029902. Thus, control limits needed to be revised again, using only the data from July 2012 to September 2014 (sample 15 to 23). The new control chart parameters are:

Table 4.11: New control limits for U chart of average rate of medical device adverse events per incident from July 2012 to September 2014.

Sample Number, i	**Month/Year**	**Total Number of Incidents case, n_i**	$CL = \bar{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \bar{U} + 3\sqrt{\frac{\bar{U}}{n_i}}$	$UCL = \bar{U} - 3\sqrt{\frac{\bar{U}}{n_i}}$
After recommendation from Department of Health					
15	Jul 2012 - Sep 2012	352,663	$CL = \bar{U} = \frac{\sum_{i=15}^{23} C_i}{\sum_{i=15}^{23} n_i} = \frac{98{,}997}{3{,}557{,}908} = 0.027824$	0.028667	0.026982
16	Oct 2012 - Dec 2012	369,182		0.028648	0.027001
17	Jan 2013 - Mar 2013	382,496		0.028634	0.027015
18	Apr 2013 - Jun 2013	388,969		0.028627	0.027022
19	Jul 2013 - Sep 2013	391,992		0.028624	0.027025
20	Oct 2013 - Dec 2013	402,393		0.028613	0.027036
21	Jan 2014 - Mar 2014	410,628		0.028605	0.027044
22	Apr 2014 - Jun 2014	426,547		0.028591	0.027058
23	Jul 2014 - Sep 2014	433,038		0.028585	0.027064

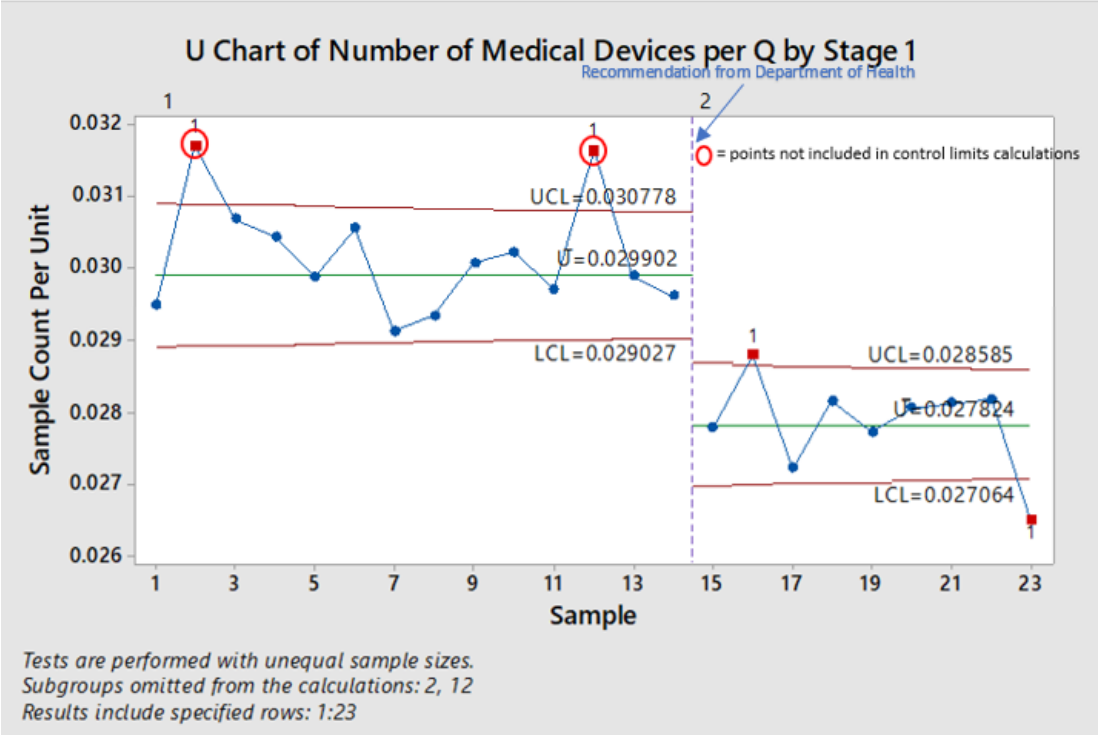

Figure 4.8: New control limits on the average rate of medical device adverse events per incident for the data in Table 4.11.

Figure 4.8 shows the control charts with these new parameters. There are two points fall below and above the control limits, sample 16 (Oct 2012 - Dec 2012) and 23 (Jul 2014 - Sep 2014); therefore, the process is not in control. From the inspection of the data from sample 16 indicates the unusual high average rate of medical device adverse events was due to the failure of public access defibrillator and external pacemaker with epicardial pacing wires. And action has been for suggested by MHRA to avoid similar incident from happening. There is no special cause can be determined for the out-of-control signal from sample 23; therefore, this sample will be retained. Thus, sample 16 will be omitted, and the new revised control limits are calculated as:

$$CL = \bar{U} = \frac{\sum_{i=15}^{15} C_i + \sum_{i=17}^{23} C_i}{\sum_{i=15}^{15} n_i + \sum_{i=17}^{23} n_i} = \frac{88{,}370}{3{,}188{,}726} = 0.027713$$

Table 4.12: Revised control limits for U chart of average rate of medical device adverse events per incident from July 2012 to September 2014 (sample 15 to 23).

Sample Number, i	**Month/Year**	**Number of Incidents case, n_i**	$CL = \overline{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \overline{U} + 3\sqrt{\frac{\overline{U}}{n_i}}$	$UCL = \overline{U} - 3\sqrt{\frac{\overline{U}}{n_i}}$
After recommendation from Department of Health					
15	Jul 2012 - Sep 2012	352,663	$CL = \overline{U} = 0.027713$	0.028554	0.026872
16	Oct 2012 - Dec 2012	369,182		0.028535	0.026891
17	Jan 2013 - Mar 2013	382,496		0.028521	0.026906
18	Apr 2013 - Jun 2013	388,969		0.028514	0.026912
19	Jul 2013 - Sep 2013	391,992		0.028511	0.026916
20	Oct 2013 - Dec 2013	402,393		0.028501	0.026926
21	Jan 2014 - Mar 2014	410,628		0.028493	0.026934
22	Apr 2014 - Jun 2014	426,547		0.028478	0.026949
23	Jul 2014 - Sep 2014	433,038		0.028472	0.026954

The revised CL and control limits are shown on the control chart in Figure 4.9. The sample 16 is not excluded from the control chart, but they have been omitted from calculations of control limits, the process now is in control. The revised control limits in Table 4.12 and Figure 4.9 can be used for monitoring the further data (sample 24 to 39) and to test whether the second process change (partnership of NHS and MHRA) has improved the stable process to successfully reduce the rate of medical device adverse events (Phase II analysis).

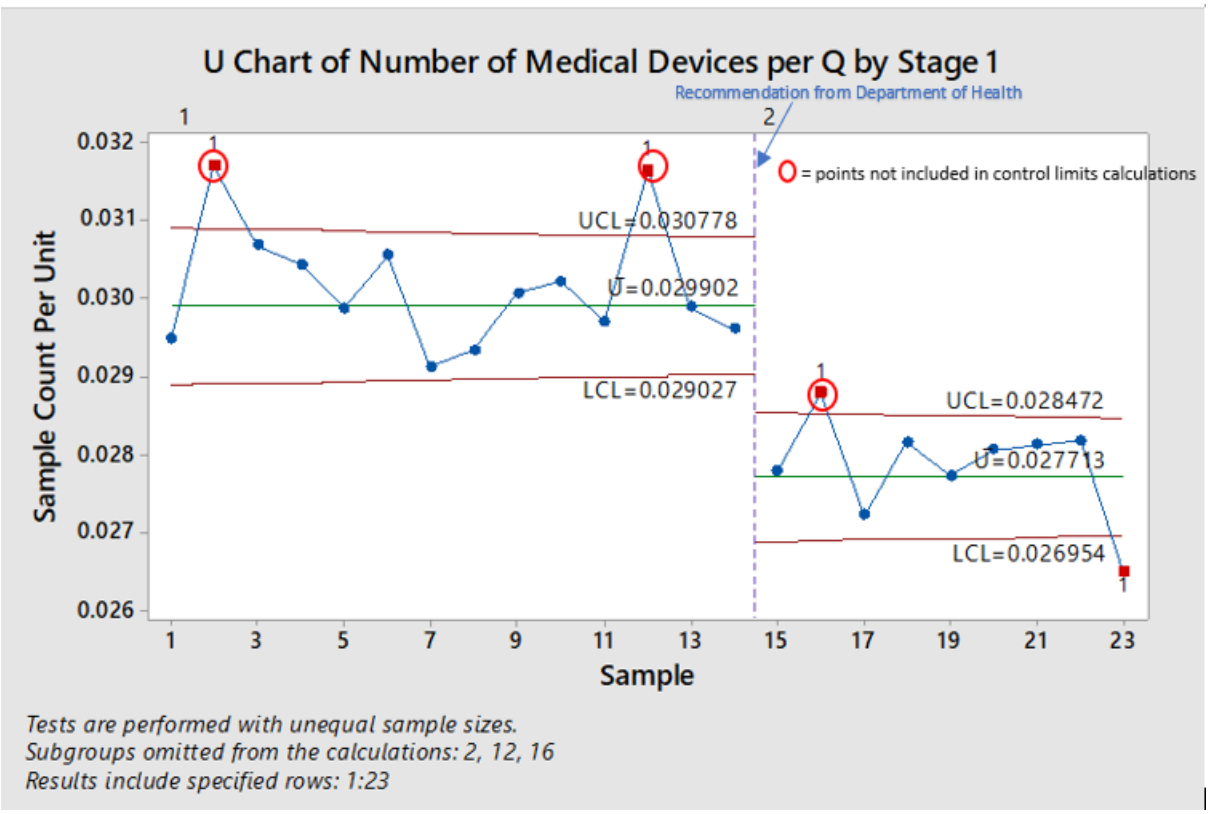

Figure 4.9: Revised control limits on the average rate of medical device adverse events per incident for data in Table 4.12.

Table 4.13 contains data on average rate of medical device adverse events per incident after the NHS and MHRA form partnership from October 2014 to September 2018 (sample 24 to 39). These data are plotted in Figure 4.10 on the continuation of the U chart developed in Figure 4.9.

Table 4.13: Continuation of data from October 2014 to September 2014 by using $\bar{U} = 0.027713$ which get from Table 4.12.

Sample Number, i	**Month/Year**	**Number of Incidents case, n_i**	$CL = \bar{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \bar{U} + 3\sqrt{\frac{\bar{U}}{n_i}}$	$UCL = \bar{U} - 3\sqrt{\frac{\bar{U}}{n_i}}$
After NHS and MHRA partnership					
24	Oct 2014 - Dec 2014	447,730	$CL = \bar{U} = 0.027713$	0.028460	0.026967
25	Jan 2015 - Mar 2015	445,612		0.028461	0.026965
26	Apr 2015 - Jun 2015	458,389		0.028451	0.026976
27	Jul 2015 - Sep 2015	456,879		0.028452	0.026974
28	Oct 2015 - Dec 2015	470,620		0.028441	0.026985
29	Jan 2016 - Mar 2016	485,585		0.028430	0.026997
30	Apr 2016 - Jun 2016	492,567		0.028425	0.027002
31	Jul 2016 - Sep 2016	494,376		0.028424	0.027003
32	Oct 2016 - Dec 2016	497,922		0.028421	0.027006
33	Jan 2017 - Mar 2017	505,035		0.028416	0.027011
34	Apr 2017 - Jun 2017	506,818		0.028415	0.027012
35	Jul 2017 - Sep 2017	520,971		0.028405	0.027021
36	Oct 2017 - Dec 2017	526,561		0.028402	0.027025

37	Jan 2018 - Mar 2018	537,875		0.028394	0.027032
38	Apr 2018 - Jun 2018	533,408		0.028397	0.027029
39	Jul 2018 - Sep 2018	517,438		0.028408	0.027019

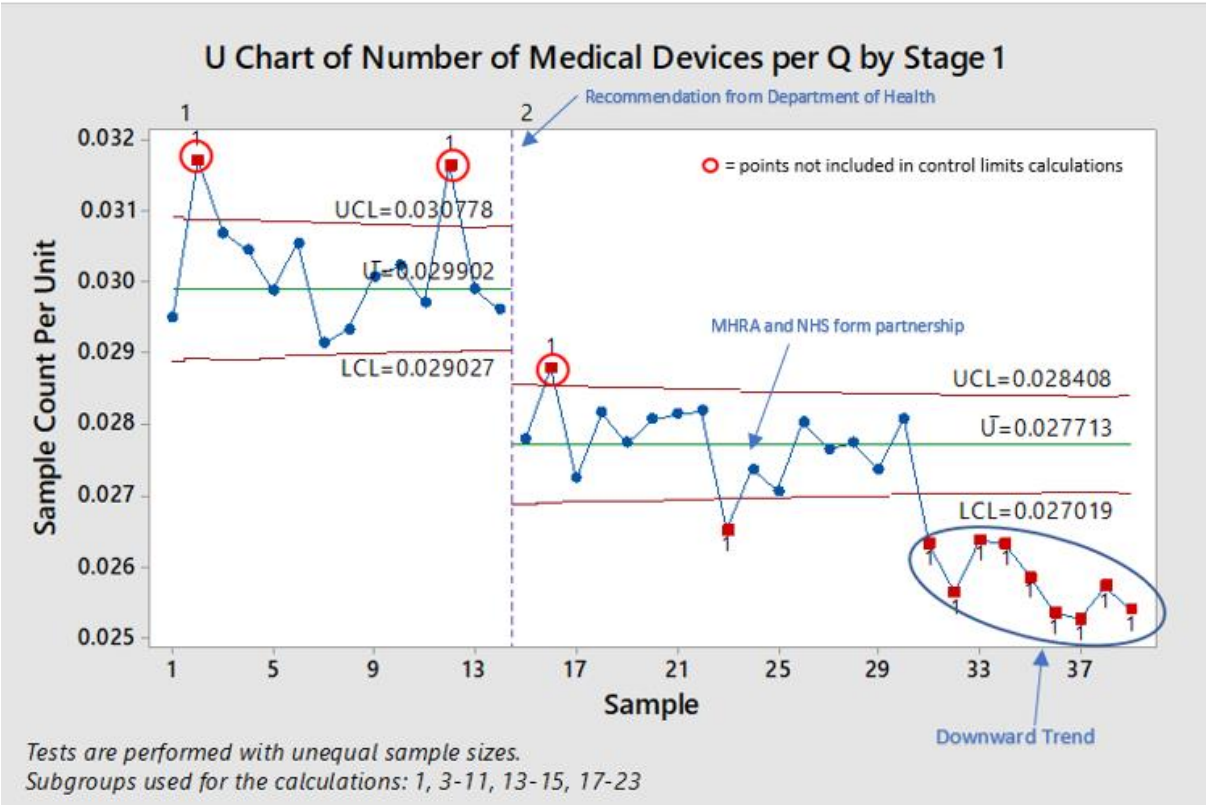

Figure 4.10: Continuation of U chart in Figure 4.9.

Figure 4.10 indicates the process are out-of-control and chart shows there is a downward shift since July 2016 (sample 31), which probably a sign of process has shifted during the period from July 2016 to September 2018. It shows there is an improvement; however, might not due to the partnership of NHS and MHR formed in September 2014, but to some other factor that began in July 2016. Since there is an improvement, it seems logical revised the control limit again, by eliminating the data from July 2016 to September 2018 (sample 31 to 39). This result in new control chart parameters:

Table 4.14: New revised control limits for U chart of average rate of medical device adverse events per incident from July 2016 to September 2018 (sample 31 to 39).

Sample Number, i	**Month/Year**	**Number of Incidents case, n_i**	$CL = \overline{U} = \frac{\sum_{i=1}^{m} C_i}{\sum_{i=1}^{m} n_i}$	$UCL = \overline{U} + 3\sqrt{\frac{\overline{U}}{n_i}}$	$UCL = \overline{U} - 3\sqrt{\frac{\overline{U}}{n_i}}$
31	Jul 2016 - Sep 2016	494,376	$CL = \overline{U} = \frac{\sum_{i=31}^{39} C_i}{\sum_{i=31}^{39} n_i} = \frac{119{,}646}{4{,}640{,}404} = 0.025784$	0.026469	0.025098
32	Oct 2016 - Dec 2016	497,922		0.026466	0.025101
33	Jan 2017 - Mar 2017	505,035		0.026461	0.025106
34	Apr 2017 - Jun 2017	506,818		0.026460	0.025107
35	Jul 2017 - Sep 2017	520,971		0.026451	0.025116
36	Oct 2017 - Dec 2017	526,561		0.026447	0.025120
37	Jan 2018 - Mar 2018	537,875		0.026440	0.025127
38	Apr 2018 - Jun 2018	533,408		0.026443	0.025124
39	Jul 2018 - Sep 2018	517,438		0.026453	0.025114

Figure 4.11 indicate the complete control chart. It shows that the process has shifted to a new level of performance immediately after recommendation from Department of Health after June 2012 (sample 14), from $\overline{U}$ = 0.029902 to 0.027713. In addition, it also shows the average rate of medical device adverse events per incident has reduced from $\overline{U}$ = 0.027713 to 0.025784 during July 2016 to September 2018 (sample 31 to 39), and the process is stable for this period. However, the reduction was not due to the partnership of NHS and MHRA that formed after September 2014 (sample 24), but to some other factor that began in July 2016. Thus, the partnership of

MHRA and NHS does not appear to have any impact on reducing the average rate of medical device adverse events. Although the partnership did not lead to improvement, the control chart can help NHS to prevent wasted investments in implementing ineffective change. The control chart does not indicate lack of control for the period of July 2016 to September 2018 (sample 31 to 39). Since the process for these period exhibits only common cause variation, if MHRA and NHS want to lower the average rate of medical device adverse events per incident and reduce the variation, it is appropriate to further investigate and devise other improvement strategies. The next step for the MHRA and NHS is thus to examine an improvement idea, continue to use the control chart to compare new process with the current measurements, and to determine whether the process has improved, constant or become worse.

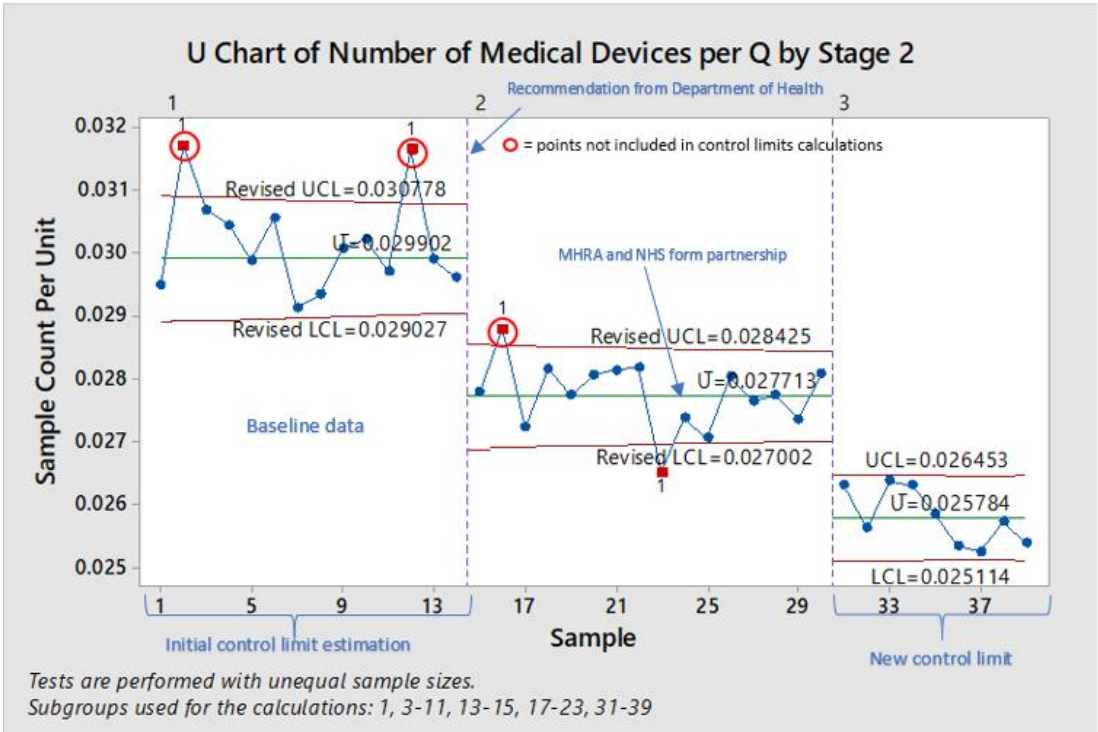

Figure 4.11: Complete U chart on average rate of medical device adverse events per incident.

4.3 Number of patient-safety-related deaths

4.3.1 Introduction

Hospital deaths are inevitable events for some terminally ill patients and are growingly being regarded as a patient safety indicator. Thus, recognizing and analysing the potential avoidable deaths should always be a prime concern for monitoring the safety and quality of healthcare system. In 2001, National Patient Safety Agency (NPSA), a Special Health authority, has established in NHS across in England in order to better address the problem and issues of patient safety and to improve the patient safety. NPSA was responsible to established National Reporting and Learning System (NRLS) that collect patient safety incident (PSIs) reports from all NHS organizations to analyse and learn from all type of patient safety incidents (Baron, 2009). The data can assist organization to identify how and where incidents take place in order to prevent them in the future. A Patient Safety Incidents (PSIs) has been defined by NHS as 'any unexpected or unintended incident which did or could have led to harm for one or more patients receiving NHS healthcare' (NHS England, 2017c). The reporting system are used to identify and analyse the emerging incident patterns and trends at a national level, so that patient safety alert will be issued by NPSA quickly to notify the healthcare system of possible risk or harm. The alert will provide an appropriate guidance to organization on preventing potential incidents that lead to harm or death. In order to streamline and integrate the functions related to safety improvement and quality, and to ensure the existing function are delegated closer to the front line, the UK government plan to better align the NHS organization with the rest of social and health care. Thus, NPSA ceased to exist as an organization in June 2012 and all the key functions and responsibility for patient safety has transferred to the NHS Commissioning Board Authority (NHS CBA). This will ensure the patient safety lie at the centre of the NHS and will build on skill and knowledge that developed by the NPSA, to drive patient safety improvement (NHS England, 2012). In November 2013, NHS has set out new plans to improve the safety of patient (NHS England, 2013). The plans include:

(i) Establish Patient Safety Collaboration Programs to gather frontline staffs, specialists, patients, professionals and others together to identify and address specific safety issues and learn from each other to enhance patient safety and quality of health care.

(ii) Launch an NHS Improvement Fellows Programme to form a representative group of fellow, with expert knowledge, experience and skills to assist the collaboratives in devising and implementing solutions.

(iii) Re-published the Patient Safety Alerts System by providing a clearer and simple framework or guidance for organisations to recognize problems and issues; and take quick action to reduce risks of patient safety.

In addition, several new changes for healthcare organizations take effect from 1st of April 2016 (NHS Confederation, 2016). This include:

(i) UK government has launched NHS Improvement (NHSI), a national improvement organization, which responsible for supervising NHS trusts, foundation trusts and independent provider. It supports providers to give high quality and safer healthcare system.

(ii) NHS launched Healthcare Safety Investigation Branch (HSIB), which will provide guidance and support to NHS organizations on investigations.

Control chart can be used to monitor the number of death and to analyse whether the intervention has successfully improved the patient safety.

4.3.2 Methods

All reported incidents happening between 1 January 2010 to 30 September 2018 were extracted from the NRLS database on 10 July 2019 using Excel 2016 and Minitab 18. NRLS has compiled and summarized the data submitted by all NHS organizations, patients, practitioners, nurse and staff, and then published the National Patient Safety Incident Reports quarterly. All reports with outcome of death were studied and analysed using Minitab 18. Since the sample size are constant for each data point, NP chart (based on the binomial distribution) was selected for monitoring number of deaths in patient safety related incidents. The procedures to construct NP chart included:

Step 1: Identify dataset

(i) Calculate the death rate for i[th] subgroup, $\hat{p}_i = \frac{D_i}{n}$

Table 4.15: Data for the number of deaths per 100,000 incidents, n=100,000.

Sample Number	Year	Number of Death per 100,000 incidents, $D_i = n\hat{p}_i$	Death rate, $\hat{p}_i = \frac{D_i}{n}$
Before NPSA ceased			
1	Jan 2010 - Mar 2010	224	0.00224
2	Apr 2010 - Jun 2010	242	0.00242
3	Jul 2010 - Sep 2010	265	0.00265
4	Oct 2010 - Dec 2010	264	0.00264
5	Jan 2011 - Mar 2011	226	0.00226
6	Apr 2011 - Jun 2011	220	0.00220
7	Jul 2011- Sep 2011	209	0.00209
8	Oct 2011 - Dec 2011	249	0.00249
9	Jan 2012 - Mar 2012	258	0.00258
10	Apr 2012 - Jun 2012	269	0.00269
SUM		2,426	0.024260
Average		$n\bar{p} = \frac{\sum_{i=1}^{10} D_i}{10}$ = 242.60	$\bar{p} = \frac{1}{10}\sum_{i=1}^{10} \hat{p}_i$ = 0.0024260
After NPSA ceased			
11	Jul 2012 - Sep 2012	238	0.00238
12	Oct 2012 - Dec 2012	231	0.00231
13	Jan 2013 - Mar 2013	266	0.00266
14	Apr 2013 - Jun 2013	271	0.00271
15	Jul 2013 - Sep 2013	259	0.00259
SUM		1,265	0.012650
Average		$n\bar{p} = \frac{\sum_{i=11}^{15} D_i}{5}$ = 253.00	$\bar{p} = \frac{\sum_{i=11}^{15} \hat{p}_i}{5}$ = 0.00253
After NHS established new plans			
16	Oct 2013 - Dec 2013	228	0.00228
17	Jan 2014 - Mar 2014	240	0.00240
18	Apr 2014 - Jun 2014	222	0.00222
19	Jul 2014 - Sep 2014	212	0.00212

20	Oct 2014 - Dec 2014	219	0.00219
21	Jan 2015 - Mar 2015	220	0.00220
22	Apr 2015 - Jun 2015	214	0.00214
23	Jul 2015 - Sep 2015	217	0.00217
24	Oct 2015 - Dec 2015	225	0.00225
25	Jan 2016 - Mar 2016	259	0.00259
SUM		2,256	0.02256
Average		$n\bar{p} = \frac{\sum_{i=16}^{25} D_i}{10}$ = 225.60	$\bar{p} = \frac{\sum_{i=16}^{21} \hat{p}_i}{6}$ = 0.002256
After NHS launched NHS Improvement and HSIB			
26	Apr 2016 - Jun 2016	234	0.00234
27	Jul 2016 - Sep 2016	222	0.00222
28	Oct 2016 - Dec 2016	238	0.00238
29	Jan 2017 - Mar 2017	242	0.00242
30	Apr 2017 - Jun 2017	224	0.00224
31	Jul 2017 - Sep 2017	216	0.00216
32	Oct 2017 - Dec 2017	237	0.00237
33	Jan 2018 - Mar 2018	236	0.00236
34	Apr 2018 - Jun 2018	218	0.00218
35	Jul 2018 - Sep 2018	207	0.00207
SUM		2,274	0.02274
Average		$n\bar{p} = \frac{\sum_{i=26}^{35} D_i}{10}$ = 227.40	$\bar{p} = \frac{\sum_{i=26}^{35} \hat{p}_i}{10}$ = 0.0022740

Step 2: Determining the baseline parameters (Data before NPSA ceased)

(i) Compute the value of centre line (CL), the upper control limit (UCL) and lower control limit (LCL).

$$CL = n\bar{p} = \frac{\sum_{i=1}^{m} D_i}{m}$$

$$UCL = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$LCL = n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$$

Table 4.16: CL, UCL and LCL for NP chart of number of deaths per 100,000 incidents (Before NPSA ceased)

Sample Number	Year	Number of Death, $D_i = n\hat{p}_i$	Death rate, $\hat{p}_i = \frac{D_i}{n}$	$CL = n\bar{p}$	UCL	LCL
Before NPSA ceased						
1	Jan 2010 - Mar 2010	224	0.00224	242.6000	289.2702	195.9298
2	Apr 2010 - Jun 2010	242	0.00242			
3	Jul 2010 - Sep 2010	265	0.00265			
4	Oct 2010 - Dec 2010	264	0.00264			
5	Jan 2011 - Mar 2011	226	0.00226			
6	Apr 2011 - Jun 2011	220	0.00220			
7	Jul 2011- Sep 2011	209	0.00209			
8	Oct 2011 - Dec 2011	249	0.00249			
9	Jan 2012 - Mar 2012	258	0.00258			
10	Apr 2012 - Jun 2012	269	0.00269			

(ii) Plot the $n\hat{p}_i$, CL, UCL and LCL values on the same graph (Figure 4.12 to Figure 4.17 plots the control chart constructed by Minitab).

4.3.3 Data Discussion

Between January 2010 to June 2012 (before NPSA ceased as legal entity), there were total 2,426 deaths and the average number of deaths per 100,000 incidents was 242.60. The NP chart with the center line at $n\bar{p}$ = 242.60, UCL = 289.2702 and LCL = 195.9298 is shown in Figure 4.12. There are not out of control observation on the control chart; thus, the process is in control during the period from January 2012 to June 2012 (sample 1 to 10) and these limits can be adopted to test whether the first process change (NPSA ceased) has improve the stable process (Phase II analysis).

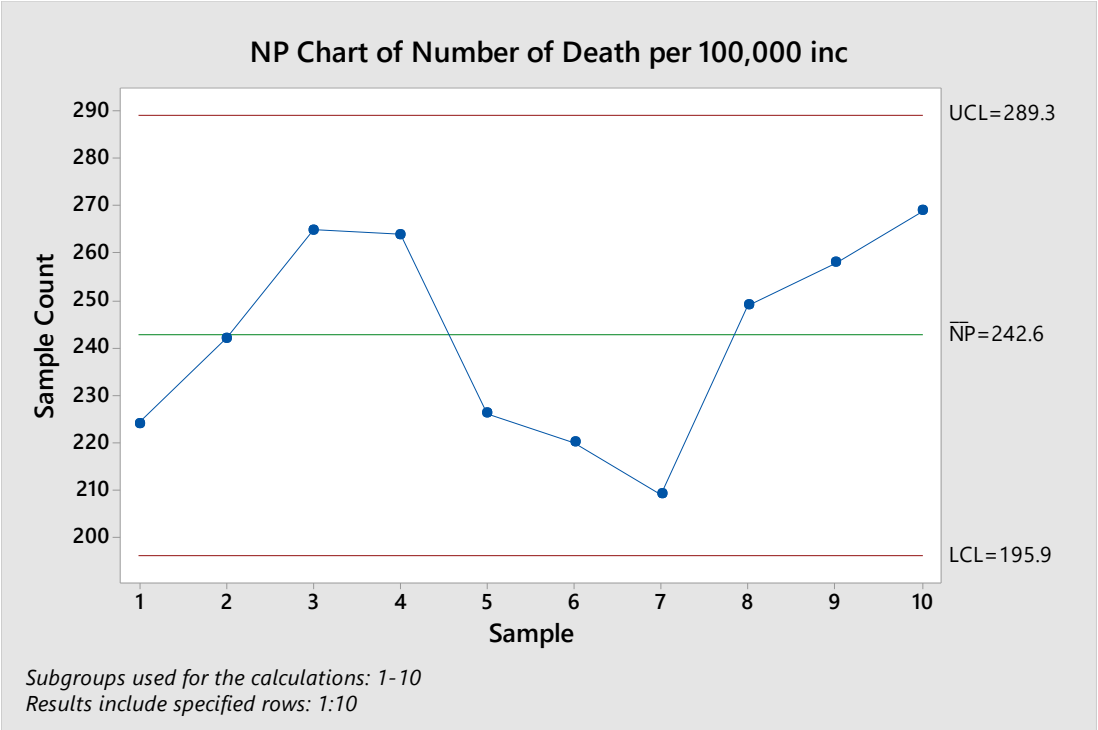

Figure 4.12: NP Chart for the data before NPSA ceased as a legal entity for the data in Table 4.16.

Table 4.15 contains data on average number of deaths after NPSA ceased as legal entity, from July 2012 to September 2013 (sample 11 to 15). These data are plotted in Figure 4.13 on the continuation of the NP chart developed in Figure 4.12.

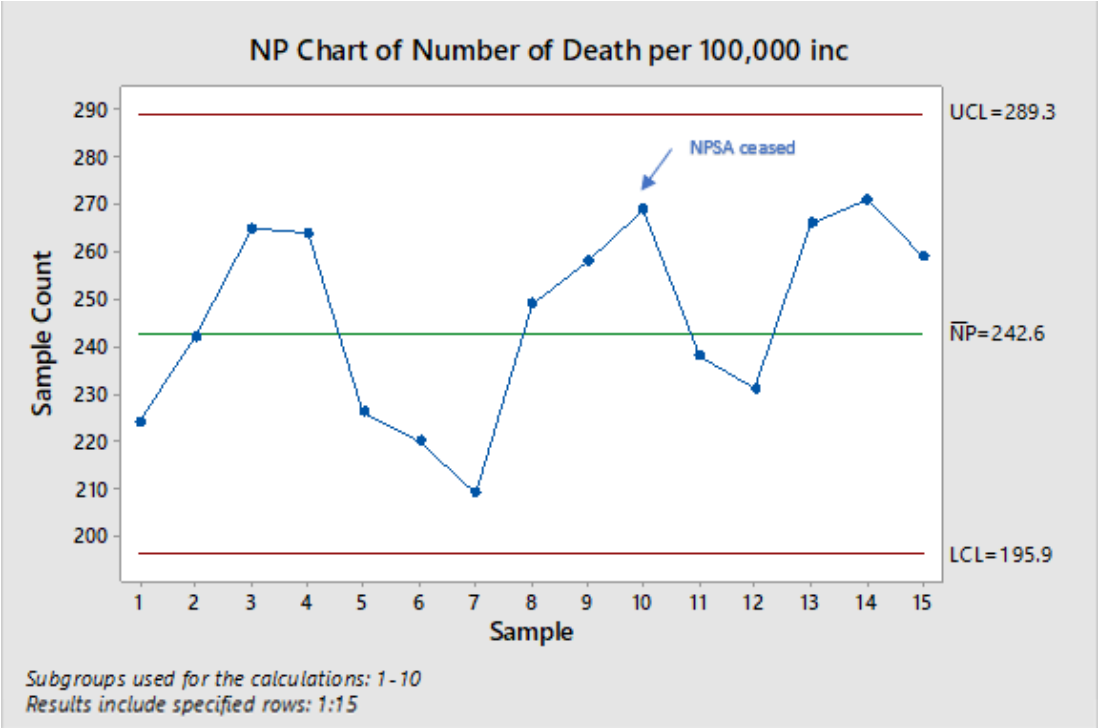

Figure 4.13: Continuation of the NP chart in Figure 4.12.

The control chart in Figure 4.13 does not indicate lack of control, and this change does not appear to have any effect on reducing the number of deaths. Since the process are stable and in control, the control limits can be adopted for test whether the second process change (NHS established new plans) has impact in improving the process. Table 4.15 consist the data on average number of deaths after NHS implement new plans, from October 2013 to March 2016 (sample 16 to 25). These data are plotted in Figure 4.14 on the continuation of the NP chart developed in Figure 4.13.

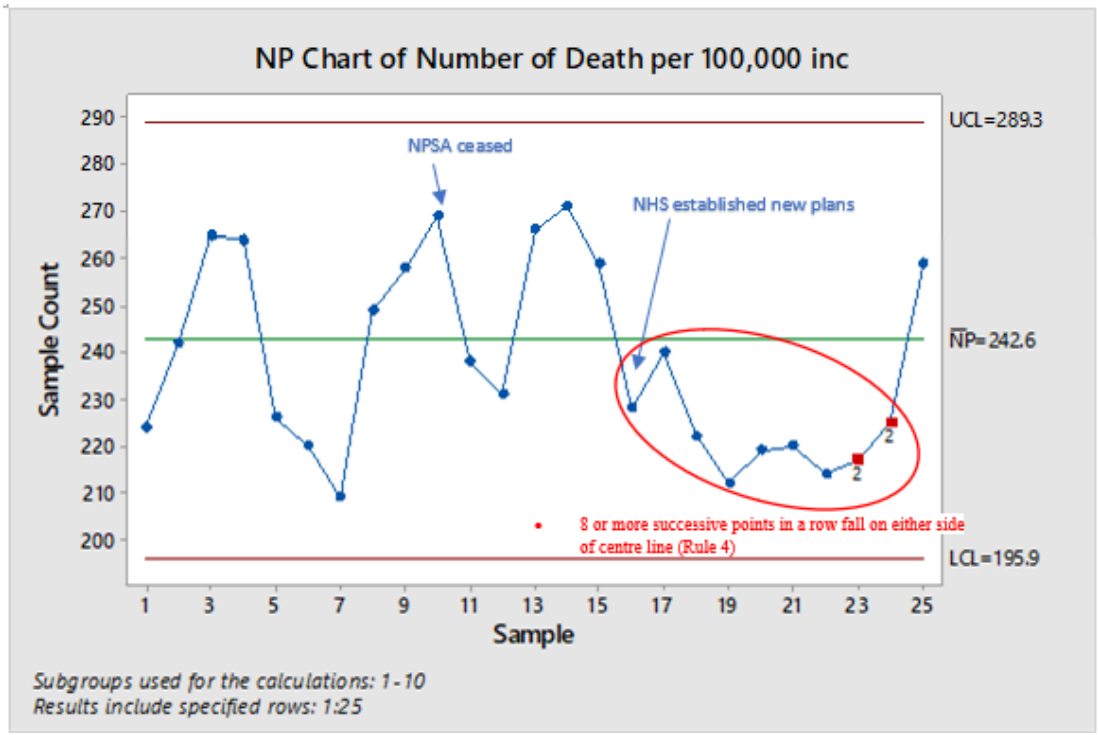

Figure 4.14: Continuation of the NP chart in Figure 4.13.

Figure 4.14 indicate that there are 9 successive data points fall below the LCL, from October 2013 to December 2015 (sample 16 to 24); thus, a special cause is detected. As shown in control chart of figure 4.14, there is a notable improvement in reducing the average number of deaths soon after the new plans were implemented by NHS. Thus, it seems logical to revise the control limits, using only the data from October 2013 to March 2016 (sample 16 to 25). The new control chart parameters are:

$$CL = n\bar{p} = \frac{\sum_{i=1}^{m} D_i}{m}$$

$$UCL = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$LCL = n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$$

Table 4.17: New control limits for NP chart of average number of deaths per 100,000 incidents from October 2013 to March 2016.

Sample Number	Year	Number of Death, $D_i = n\hat{p}_i$	Death rate, $\hat{p}_i = \frac{D_i}{n}$	$CL = n\bar{p}$	UCL	LCL
After NHS established new plans						
16	Oct 2013 - Dec 2013	228	0.00228	225.6000	270.6091	180.5909
17	Jan 2014 - Mar 2014	240	0.00240			
18	Apr 2014 - Jun 2014	222	0.00222			
19	Jul 2014 - Sep 2014	212	0.00212			
20	Oct 2014 - Dec 2014	219	0.00219			
21	Jan 2015 - Mar 2015	220	0.00220			
22	Apr 2015 - Jun 2015	214	0.00214			
23	Jul 2015 - Sep 2015	217	0.00217			
24	Oct 2015 - Dec 2015	225	0.00225			
25	Jan 2016 - Mar 2016	259	0.00259			

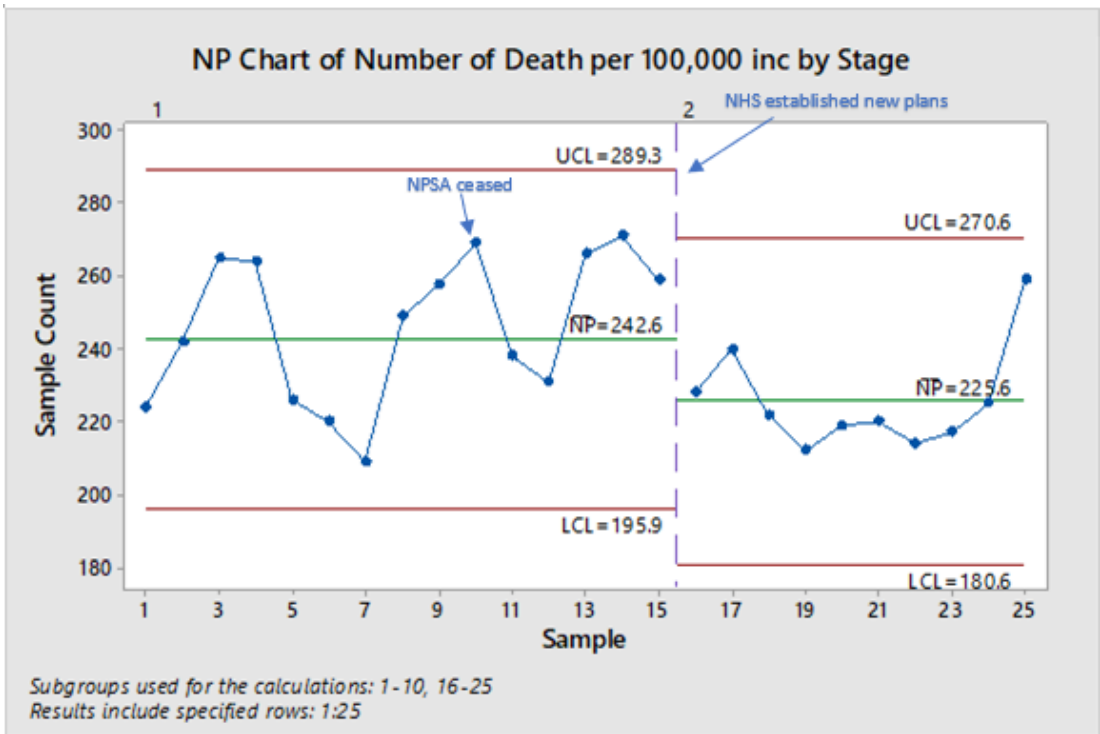

Figure 4.15: New control limits on the average number of deaths per 100,000 incidents for data in Table 4.17.

Figure 4.15 shows the control charts with these new parameters, there is no indication of an out-of-control condition is observed. Thus, the process statistically stable and the limits can be adopted to test whether the third process changes (Launch of NHS Improvement and HSIB) has effect in improving the patient safety. Table 4.15 consist the data on average number of deaths after the launch of NHS Improvement and HSIB, from April 2016 to September 2018 (sample 26 to 35). These data are plotted in Figure 4.16 on the continuation of the NP chart developed in Figure 4.15.

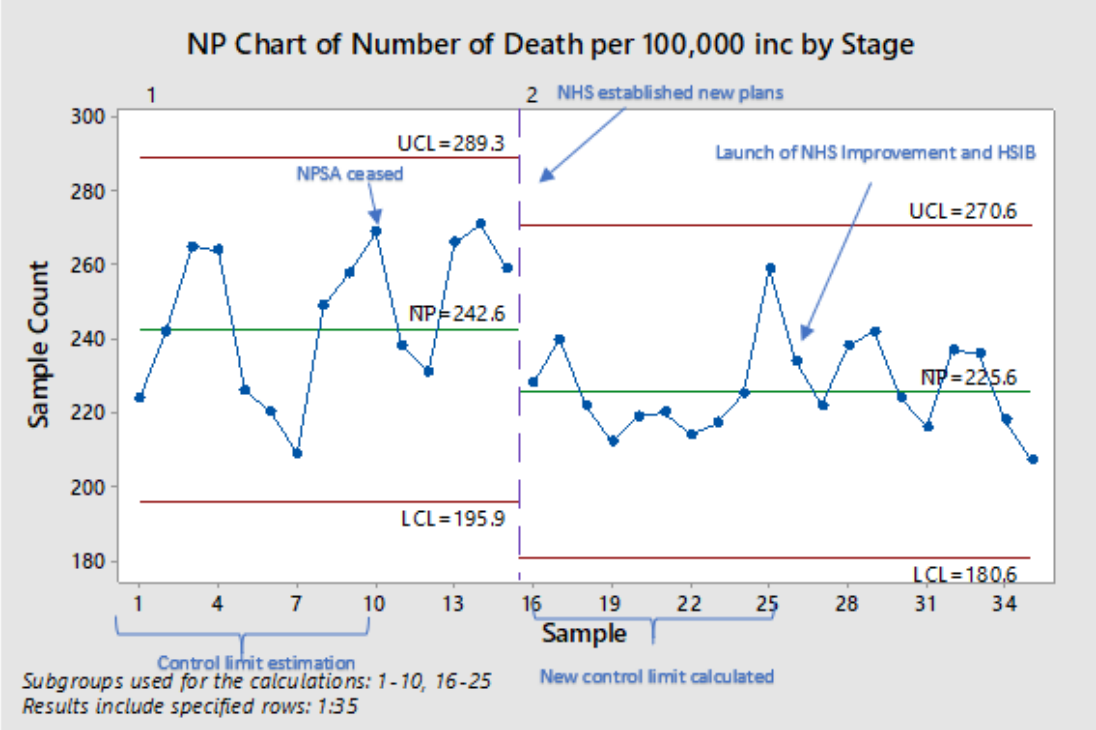

Figure 4.16: Continuation of the NP chart in Figure 4.15.

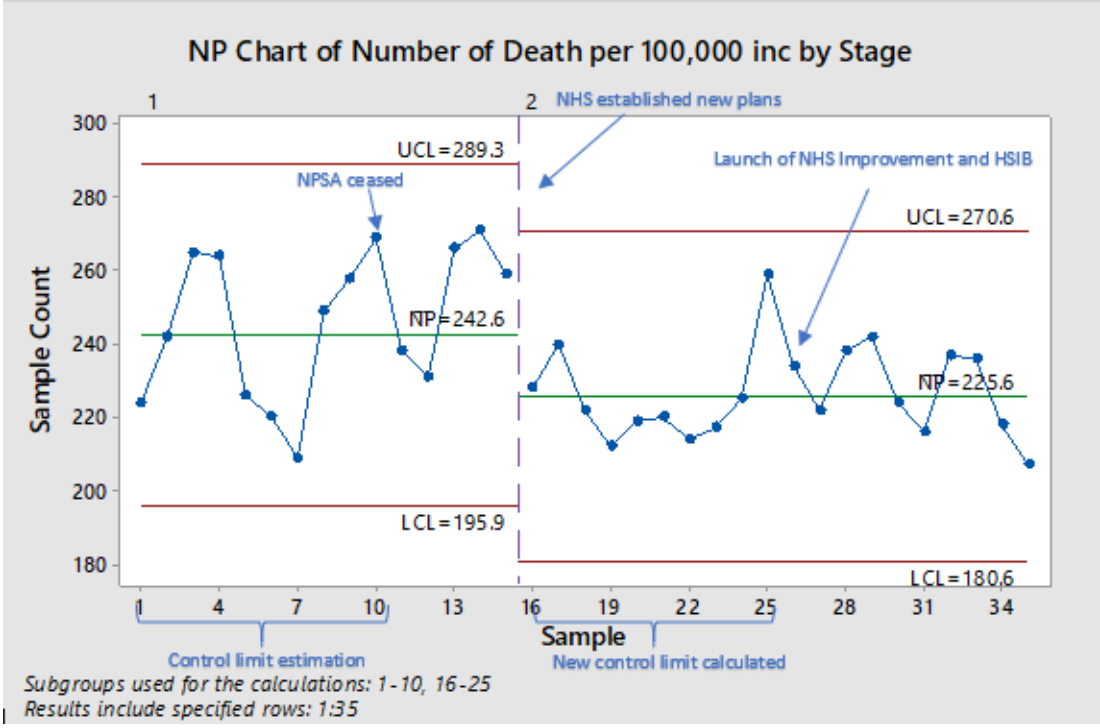

Figure 4.17: Complete NP chart on average number of deaths per 100,000 incidents.

The control chart in Figure 4.16 does not indicate lack of control, and this change does not appear to have any effect on reducing the number of deaths. Although the interference did not lead to improvement, the control chart is useful to avoid NHS from investing more resources and time in implementing unproductive or ineffective changes throughout the country. Since the process contain only common cause variation, if NHS want to improve the patient safety and reduce the variation, it is appropriate to further investigate and develop other improvement strategies.

4.4 Control Chart Methodology Discussion

The above examples illustrate common points about control charts. The main advantage of applying control charts methodology is control charts can determine whether the process is stable and to detect when significant signal or special cause of variation exist. Control charts can help healthcare institutions to prevent wasted investment in any changes that sound great but have no beneficial effect in real improvement, as the case in the medical devices/equipment incidents and number of patient-safety-related deaths examples. Furthermore, the example also indicates that how control charts can detect the shift in the process or significant signal from the data pattern faster than other statistical tools. The traditional statistical analysis method

usually is based on statistical test with all data collected into large samples that disregard the time or chronological order – for instance, the number of patient deaths after changes might be compared with the pre-change. Significant tests or hypothesis testing are the statistical tool that often used to identify whether one group is "significantly different" from another group. This method is only powerful if based on adequately large data sets; however, not everyone has the time and resources to gather and collect data on a large scale. The application of these traditional method in healthcare study often restrict by the delay in collecting adequate large-scale data and researchers may turn to adopt other simple tools such as line charts, bar graphs, pie charts or tables to shows the data. In such circumstances, researchers can only make a qualitative statement in determining whether or not the change lead to real improvement. In contrast, construction of control charts does not require as much as data as traditional method and the charts shows how the process changes or shifts over time by plotting the data in chronological order. Thus, SPC charts can detect the process trends and patterns earlier. The ambulance response time example further illustrates that how SPC charts can detect the shift in the process or significant signal from the data pattern easier and faster than other traditional statistical tools. More commonly, these examples show how control chart assist the healthcare institutions to select the appropriate or right improvement strategy- whether to search and eliminate special causes to shift process into state of control (if process is out of control) or to put more effort on fundamental process improvement and restructure or redesign the process into desirable direction (if process is in state of control). In addition, as showed in the examples above, the control chart can also be used as a simple aid or tools to monitor whether the improved process is sustained over time. Thus, control chart is useful in assisting to visualize the effectiveness of existing process performance, to take more statistical rigor to the process of making important decision and to ensure the sustainability of improvements in process over time.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

In a nutshell, control chart as a statistical analysis tool is being increasingly recommended for use in the monitoring adverse event and improvement of hospital performance due to its reliability and user-friendliness. Healthcare is always overburdened with adverse events, infections, medical error, preoperative and postoperative complications, etc. When there is more human involvement in the healthcare process, the chance or probability of error are also more. Control chart as a powerful statistical process analysis tool can helps to identify the source of error by differentiate the special and common cause of variation, each of which require a different healthcare management response. For special cause variation, management need to find the cause and act to eliminate it; however, to reduce the common cause variation, management need to restructure the underlying process system in some fundamental way. Control chart can help physician and personnel in the healthcare organizations to continuously monitor, control and improve the patient's health and enable them to utilize the objective data and statistical thinking to make suitable or appropriate decisions.

5.2 Recommendations for future work

The limitations in this research has showed the following areas as recommendations for future work:

(i) Continuously monitoring the performance：

This research indicate that control chats are useful in monitoring the process improvement in healthcare sector and in determining the impact of the process change. Thus, control charts should be used continuously to monitor the sustainability of the healthcare improvements.

(ii) Conduct primary analysis：

Since this research conduct the secondary analysis, thus we have no control over the quality of data. We should participate in data collection process for research study to have a thorough understanding of the case.

(iii) Consider other control charts:

Shewhart control charts that considered in the research are highly suggested in Phase I application for detecting large shift in the process mean. However, they are not effective in detecting smaller process shift. Thus, others control chart such as cumulative sum (CUSUM) and exponentially weighted moving average (EWMA) charts, which are sensitive in detecting small process shift in the Phase II application, should be used together with Shewhart control charts.

CHAPTER 6

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