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The Use Failure Mode and Effects Analysis as Quantitative Risk Analysis Tool

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Abstract

The use of semi-quantitative risk assessment is subjective technique to a certain degree which is dependent on the expert view in the field. This may generate as source of bias in decision making especially in the healthcare industry. This paper discusses initial attempts to transform scoring system into purely quantitative manner based on the Failure Mode and Effect Analysis (FMEA) equation after using Statistical Process Control (SPC) to construct control charts with unique parameters (mean, Upper Control Limit (UCL) and the frequency of outbreaks) for each state based on 20 years trend from 1998 to 2017. The subjects of this case study are selected outbreak trend records of some states in USA. The illness risk of each state from outbreaks will be determined by a value that will be compared with other states values to identify its rank.

Keywords: Control Charts; FMEA; SPC; UCL

Introduction

Statistical Process Control (SPC) is a valuable mean for monitor and control of specific inspection characteristics [1]. It can be used in the monitoring of the outbreak trends from various states as in the present case. Laney attribute chart was sought and found to be suitable to correct for data dispersion that cannot fit the assumed distribution for the control chart type, and this was observed herein in the dataset [2]. Failure Mode and Effect Analysis (FMEA) is a scoring technique for risk analysis and assessment [3].

FMEA: A Crucial Tool in Scientific-Based Discussion Making

Historically, the practical use of FMEA was dated for more than a half-century by USA military organization in late the 1940s. The main goal for using this technique was to minimize the number and the probability of failures which could not be fixed in machines or instruments. Later, in 1960s NASA has captured and improved the methodology to eradicate the risk of the failure of equipment that could not be repaired after takeoff of the spacecraft [4].

Literally, the detailed definition of FMEA - provided by American Society for Quality (ASQ)- could be referred to as "a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. It is a common process analysis tool. Failure modes mean the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures" [5].

FMEA can be adopted for various applications in industry, project management, services and even academic research. This technique can determine the consequences of possible failure modes by analyzing them and hence can support in establishing preventive measures. Thus, FMEA tool is an indispensable technique in decision making for maintenance and principal disbursement [6]. However, some researchers have demonstrated some drawbacks of the ordinary FMEA method, including lucidity, reliability and the power to sustain the improvement process which leads them to adopt a quantitative modification on FMEA [6].

The following working example will demonstrate the combination of SPC and quantitative FMEA (qFMEA) to assess the risk of illness-related outbreaks of randomly selected states in the USA.

A Worked Example of Quantitative Risk Assessment

An epidemiological data from 1998 to 2017 were obtained from National Outbreak Reporting System (NORS) internet platform (https://www.cdc.gov/nors/index.html) which was established in 2009 by the Centers for the Disease Control and Prevention (CDC) [7]. Records were extracted using statistical software which is available commercially in the same way described in other research works elsewhere [8, 9]. The use of statistical software programs such as Minitab® version 17.1.0 has facilitated rapid and accurate data visualization quantitatively, in addition to the interpretation and assessment of the pattern for the observed inspection properties and it is in the current case the outbreaks in selected States in the USA [10,11].

Control Charts in Outbreak Monitoring

Control chart (also known as a process-behavior chart) is an important tool in the monitoring of an inspection characteristic under observation. It provides a useful mean to visualize the pattern of data and to assess the performance quantitatively. Accordingly, it is useful SPC mean in various industries and services. Non-industrial properties also could be monitored using control charts to show a general trend that changes over time. The selected type of the trending chart in outbreak trending is attribute one but after adopting Laney modification to correct for either over or under-dispersion of data which deviate from presumed distribution. The magnitude of this spreading is indicated in the control chart generated by the program by σZ value. In outbreaks, x-axis of control chart shows the number of outbreaks arranged in chronological order from 1998 to 2017, while y-axis shows the number of illness cases per each recorded outbreak. The control chart is composed of a diagram formed by joining successive points together, mean, Upper Control Limit (UCL), Lower Control Limit (LCL) and alarming points "marked by red dots". Each red dot is marked by a number which is specific for each type of alarm. Nevertheless, the number "1" alarm is unique from others because it is indicative of the aberrant single value that is greater than the upper threshold of the trending chart. While other out-of-control points are warning for other phenomena such as a shift in the process average value or shift in the trend either toward improvement or deterioration which are still confined within the window of Control Limits (CLs). These properties of control charts are evident in Figures 1 to 6 for outbreaks of some states in the USA which have been constructed using Minitab® version 17.1.0. These states are Guam, Idaho, Louisiana, Utah, Indiana, Hawaii, Georgia, Iowa, Connecticut, Colorado, Illinois and California. The number, the threshold, the magnitude and the frequency of excursion of each state outbreak over 20 years monitoring can provide a mean for assessing the risk encountered for the population of each state.

Simplified Risk Assessment Using Quantitative Risk Probability Number (qRPN)

Accordingly, Figures 1 to 6 was produced showing the pattern of the outbreak for each state and each one possesses its own parameters. The average value could represent the severity factor (S), Upper Control Limit (UCL) is the threshold of outbreak before it is considered out-of-control considered as detectability factor (D) and finally the frequency of occurrence (O) which is the total number of outbreaks divided by the time (20 years in the present case). By calculating Risk Probability Number (RPN) using the following formula [12]: RPN = S x O x D, a numerical value is obtained which is different from state to state and a descending ranking order is shown in Figure 7. From this diagram, Illinois State is at highest risk of outbreak number of sickness followed by California while Guam and Idaho are the least in potential risk of the illness of the individuals per outbreak in the current comparison group.

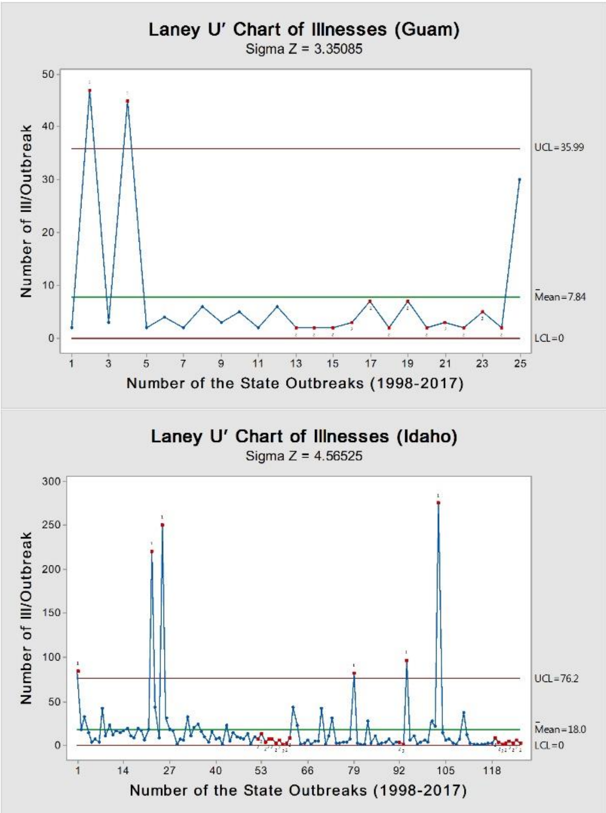

Figure 1: Laney attribute control charts for outbreak data for Guam and Idaho States over 20 years of survey study.

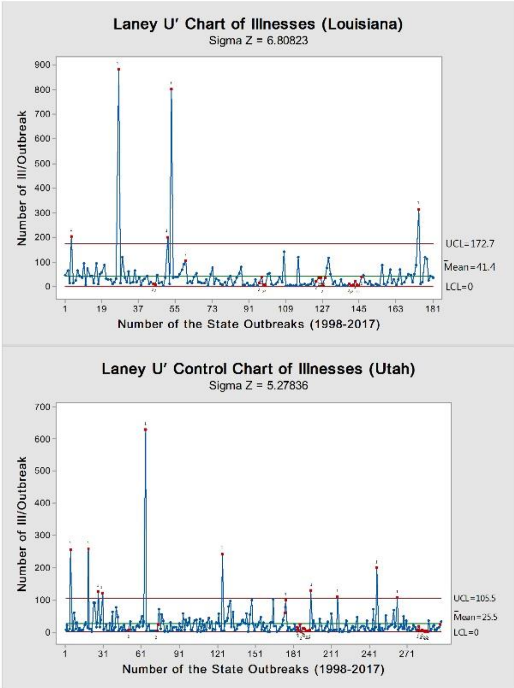

Figure 2: Laney attribute control charts for outbreak data for Louisiana and Utah States over 20 years of survey study.

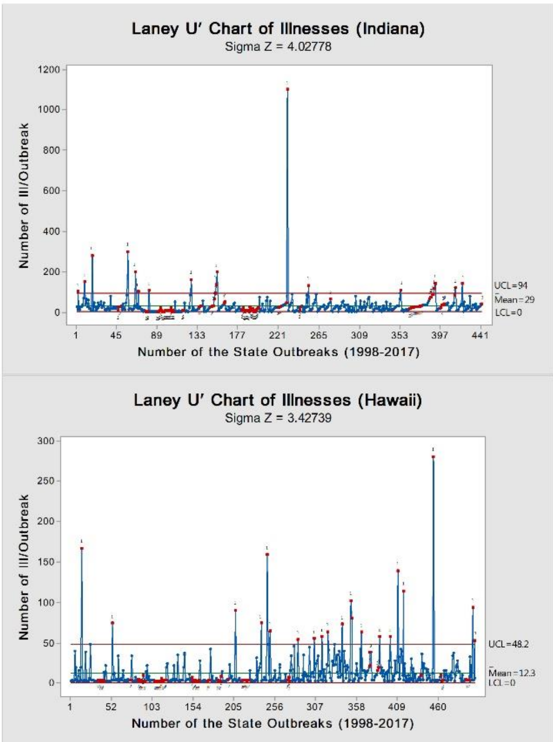

Figure 3: Laney attribute control charts for outbreak data for Indiana and Hawaii States over 20 years of survey study.

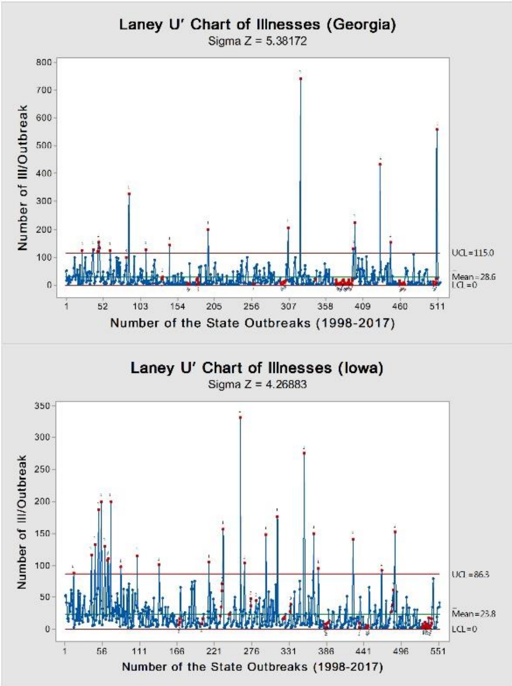

Figure 4: Laney attribute control charts for outbreak data for Georgia and Iowa States over 20 years of survey study.

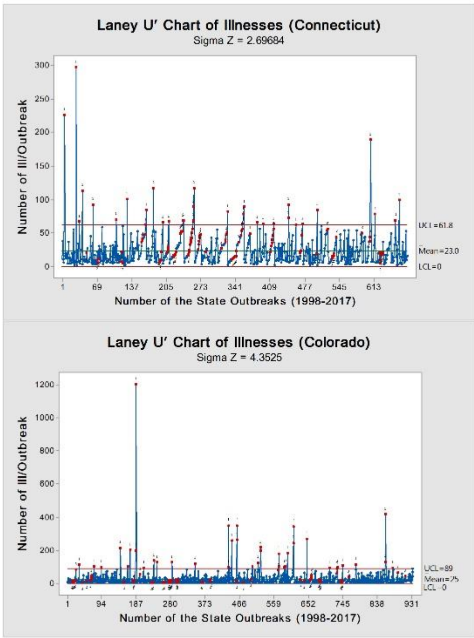

Figure 5: Laney attribute control charts for outbreak data for Connecticut and Colorado States over 20 years of survey study.

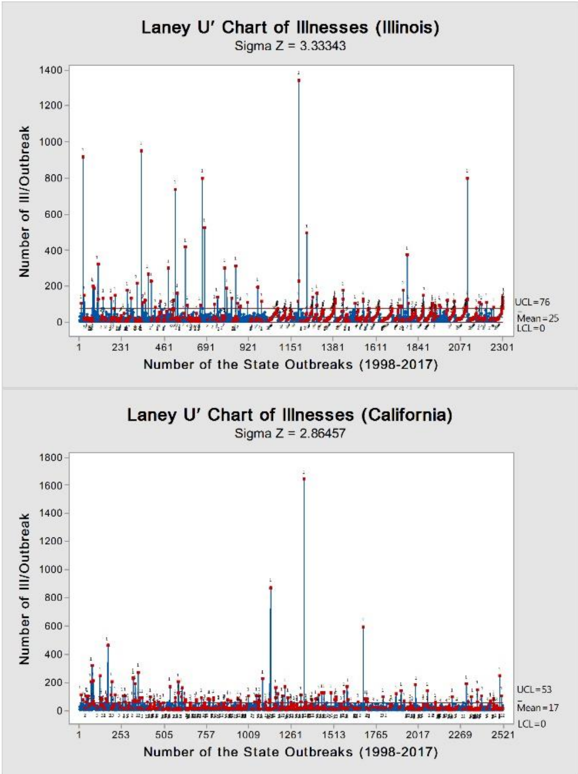

Figure 6: Laney attribute control charts for outbreak data for Illinois and California States over 20 years of survey study.

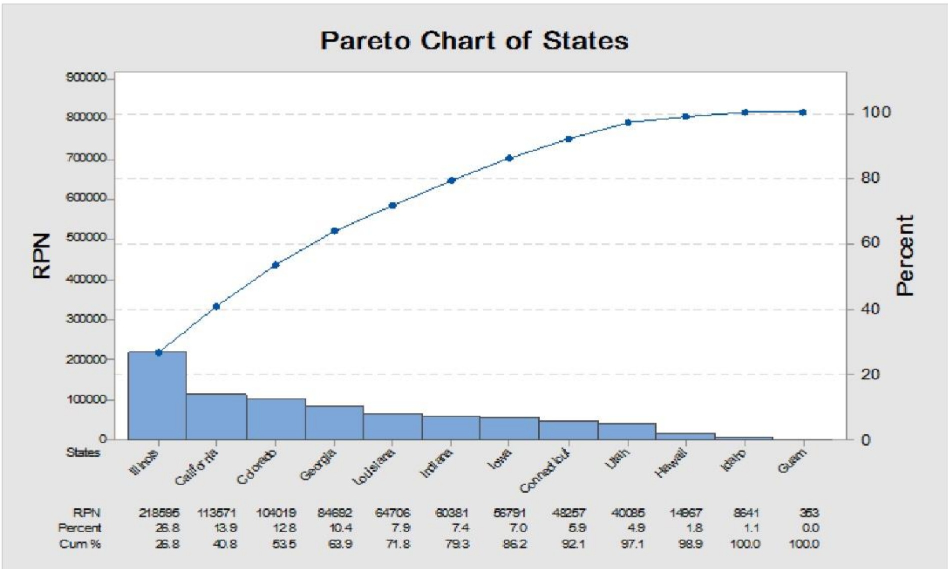

Figure 7: Pareto diagram showing descending order for the risk of outbreak illness using quantitative RPN.

RPN is normally dependent on a scoring value system which varies from project or study to another, where it can be biased and yield misleading outcome due to the influence of subjectivity. In the present case, Figure 7 for qRPN is based on factual data obtained from previous graphs of control charts. Outbreak rates, means, UCLs are all obtained from Figures 1 to 6 to give qRPN for each state based on its previous long-term history of outbreaks on a yearly basis. By updating the control charts periodically by adding current records the control charts parameters may change giving new values which could be either improving (low-risk value) or deteriorating (increasing qRPN). Accordingly, these values of qRPN is a dynamic measuring tool for assessment of the outbreak risk in each state and provide a comparison between them to show which states are at greatest risk when qRPN is combined with Pareto chart. Moreover, qRPN measures the degree of improvement or deterioration for each state with time and the effect of actions or measures taken.

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