Case Report

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Statistical process control research of toxicological outbreaks in USA: an opinion from long-term web-based trending for selected cases

Abstract

Outbreaks are an inherent problem that impacts human health quality and even life. Many recorded outbreaks in the USA are related to toxicity from exposure to toxicological agents. The regulatory agencies in the developed nations have established a rigorous and strong system for monitoring, control and documentation of such events. Accordingly, a detailed database record could be found from which a thorough analysis is conducted to derive useful data about the existing situation, expected future and improvement achieved or needed to contain the outbreak rates in the country. National Outbreak Reporting System (NORS) which is developed from the Centers for the Disease Control and Prevention (CDC) in 2009 is providing a large set of data about outbreaks in the USA. These records were processed to isolate and study the toxicological outbreaks. From this internet platform, many lessons could be learned from data analysis through observation of patterns and using statistical process control (SPC). Primarily, about 5.7% of toxicity sourced from human exposure to water and the remaining from food as a primary mode of transmission. Toxicological water sources were Sodium Hydroxide, Chlorine, Chloramine, Nitrite, Copper, Cyanotoxin and other unknown chemicals/toxins. On the other hand, food toxicity stemmed from heavy metals, Ciguatoxin, Histamine, Scombroid, Shellfish and Mycotoxin ingestion. Plant/herbal toxins were found in both food and water cases with the later mode caused 1341 toxicity cases in just one outbreak. More than 60% of toxicities originated from a chemical/toxin, Scombroid and plant/herbal sources. Corrective and preventive action (CAPA) planes should be enforced for containment of these etiological sources that cause toxicity to save citizens health. This is in turn could be supported by simple quantitative risk assessment that could be established using control charts.

Keywords: CDC, NORS, SPC, cyanotoxin, mycotoxin, ciguatoxin, scombroid

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Introduction

Epidemics have paralleled man life history on earth with their devastating consequences that have influenced the course of events across time.[1] However, in the modern era great breakthrough and advancements have been achieved in the healthcare industry and technology especially in the developed nations.[2] Nevertheless, Outbreaks appear to be unavoidable and accompanying human communities and associated with his activities.[3] However, thorough monitoring and control system coupled with appropriate containment measures are crucial to minimize the adverse impact of such annoying events.[4] Statistical process control (SPC) tools of epidemiological incidents visualize the existing status, predict the future and determine the improvements required or achieved in the examined inspection characteristics.[5,6] The ease of use of commercial statistical software packages helps in deliver on-time quantitative analysis which is useful in decision making.[7,8] Due to the challenges encountered with epidemiological events, the following case will demonstrates the simple and effective use of SPC tools in spotting major toxicological factors involved in the 20 years recorded outbreaks in USA.

Case report

An epidemiological record was extract from National Outbreak Reporting System (NORS) web site (https://www.cdc.gov/nors/index.html) which was developed by the Centers for the Disease Control and Prevention (CDC) in 2009 and providing a large set of data about outbreaks in the USA.[9] Microsoft Excel sheet was processed, filtered and data stratification was done to selectively study the toxicological outbreaks in the USA from 1998 to 2017. Commercial statistical software programs were used as previously applied in other research studies for monitoring of specific inspection characteristics.[10–12] However, Laney approach for correction of data dispersion was applied to overcome non-compliance to the assumed distribution of Poisson-type[13]. Since most of the segregated data showed distribution fitting that deviates significantly from the required underlying assumed spreading, Laney modification was used and σ Z value in Figures 1–4 of control charts indicated the level of dispersion of data. On the other hand, these figures illustrate different types of toxicological outbreaks as trends since 1998 to 2017. Red points above the mean line (average number of ill individual for each type of toxicity) of the charts are indicative of excursions in the number of outbreak illness above the normal rhythms expected for the normal trend and variability of each specific outbreak. Additionally, Upper Control Limit (UCL) can be considered as a cut-off threshold value for the number of illness cases per single outbreak. Histogram of Figure 4 is indicative of the low level of outbreak illness has occurred during the course of 20 years of observation with few exceptions of significantly aberrant outlier values for specific extraneous and assignable cases of incidents. Based on these process-behavior charts, a simple risk assessment method could be used quantitatively in the future dependent on failure modes and effects analysis (FMEA) concept.[14] Figure 5 focuses on the major causes etiological agents for toxicity-related outbreaks in the country.

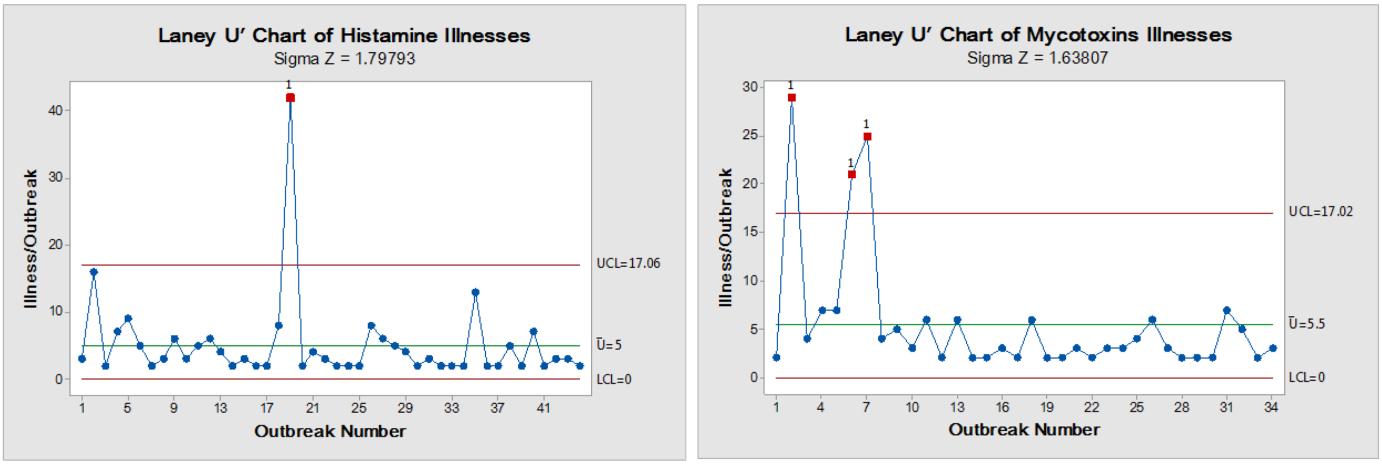

Figure 1 Laney attribute control charts for Histamine and Mycotoxin toxicity in USA over 20 years.

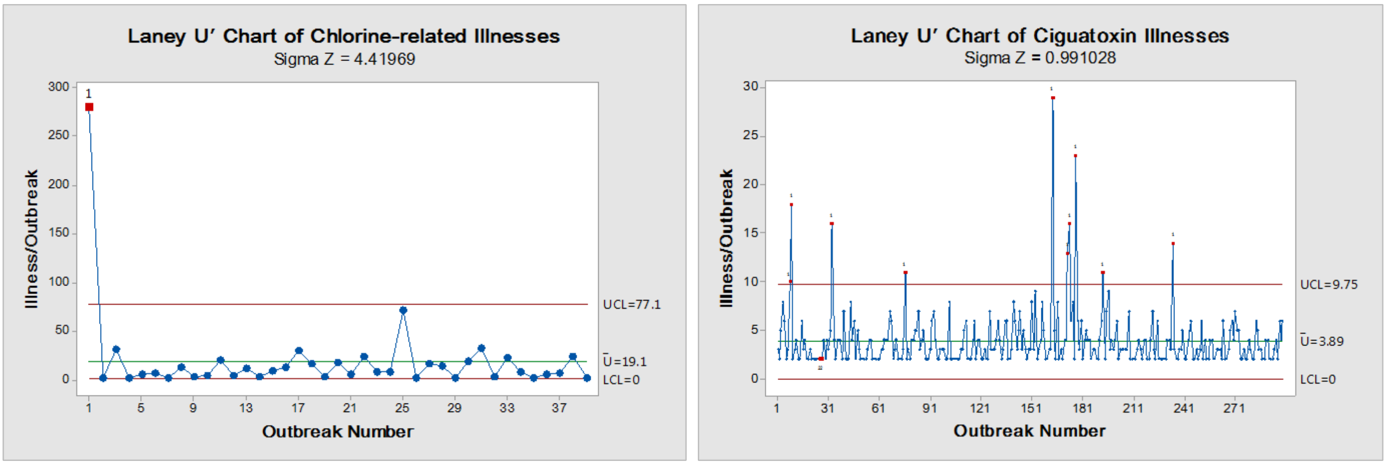

Figure 2 Laney attribute control charts for Chlorine-associated and Ciguatoxin toxicity in USA over 20 years.

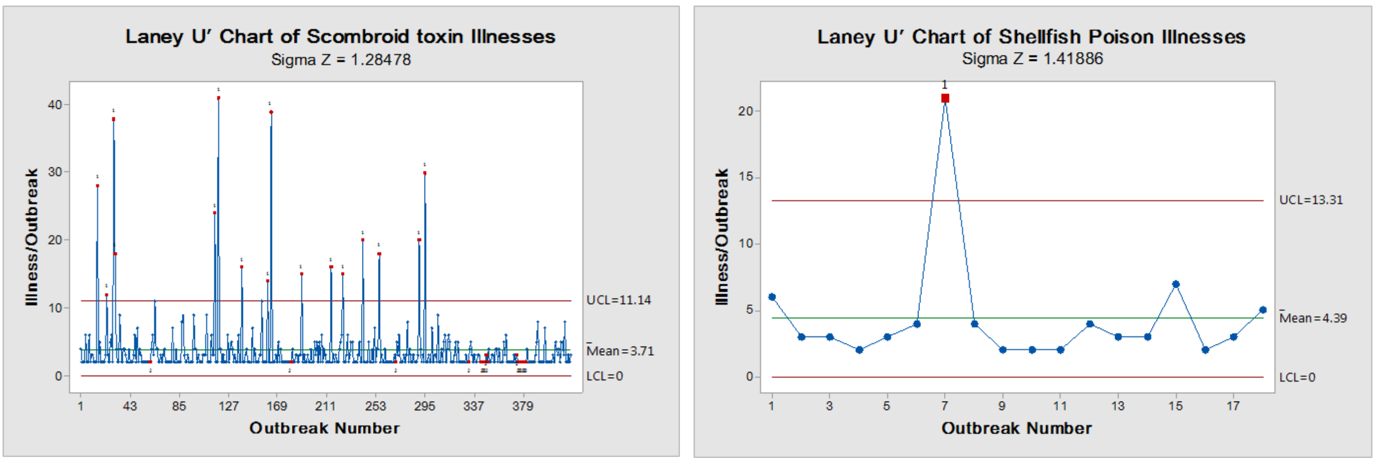

Figure 3 Laney attribute control charts for Scombroid and Shellfish toxicity in USA over 20 years.

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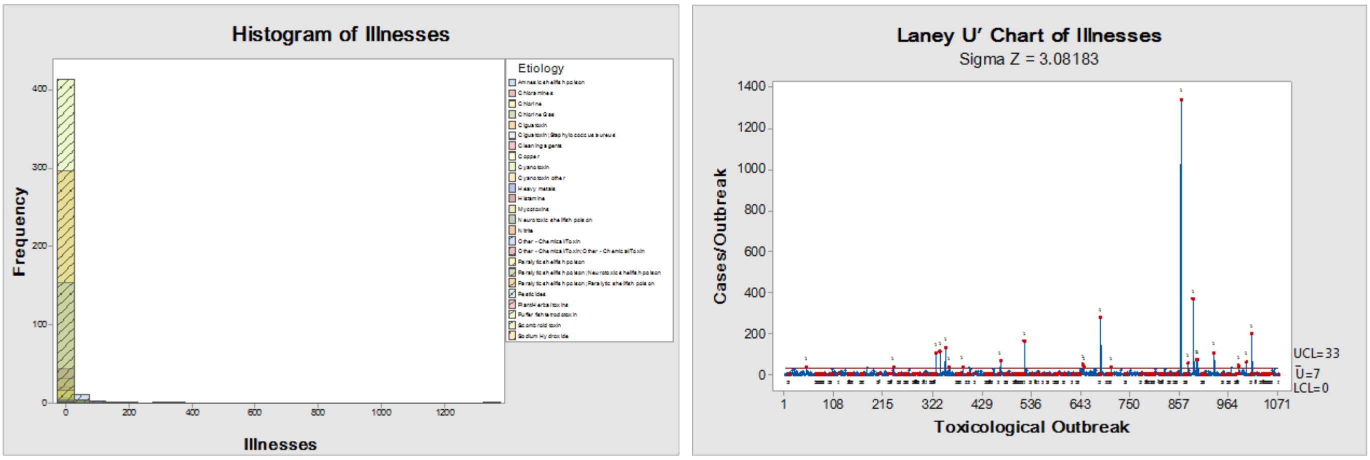

Figure 4 Histogram showing the distribution of total outbreak case from 1998 to 2017 and Process-behavior chart showing overall toxicity-associated outbreaks in USA during 20 years survey.

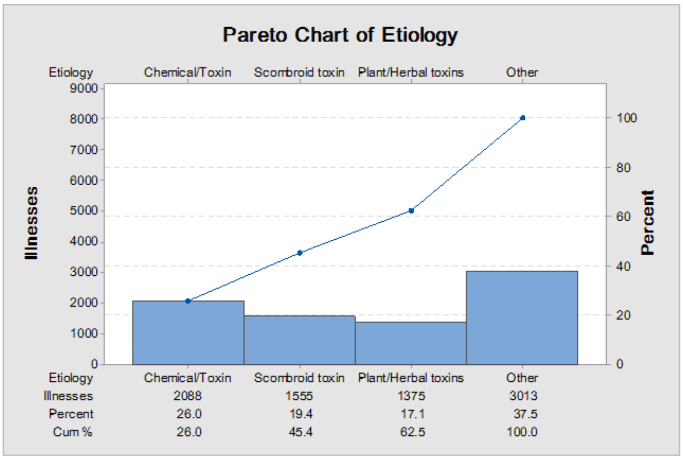

Figure 5 Pareto diagram showing major contributors of toxicological-based outbreaks during 20 years survey.

Discussion

Toxicological outbreaks have contributed roughly to about 2.3% of the overall outbreak cases in the USA. Primarily, about 5.7% of toxicity sourced from human exposure to water and the remaining from food as a primary mode of transmission. Toxicological water sources were Sodium Hydroxide, Chlorine, Chloramine, Nitrite, Copper, Cyanotoxin and other unknown chemicals/toxins. On the other hand, food toxicity stemmed from heavy metals, Ciguatoxin, Histamine, Scombroid, Shellfish and Mycotoxin ingestion. Plant/herbal toxins were found in both food and water cases with the later mode caused 1341 toxicity cases in just one outbreak. More than 60% of toxicities originated from a chemical/toxin, Scombroid and plant/herbal sources. Corrective and preventive action (CAPA) planes should be enforced for containment of these etiological sources that cause toxicity to save citizens health. Ciguatoxin and Scombroid are seafood-related toxins - produced by algae and bacteria, respectively - that contributed by about one third of toxicological-related epidemiological incidents in the country. This is a challenging obstacle that faces regulatory agencies due to misdiagnosis in addition to the absence of taste and odor for these toxins when food is consumed and ingested.[15] Toxicity with Chloramine compound from water is the most common among Chlorine-related agents toxicity. An example for simple FMEA that could be applied in a quantitative manner to the present case using control charts as the following:[16]

$$RPN = S \times O \times D \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots.. equation 1$$

Where:- RPN: Risk Priority Number, S: Severity, O: Occurrence, D: Detectability

A worked example:- Overall toxicity outbreaks during 20 years: S = 7, O = 53.75, D = 33. Accordingly, RPN= 12416 which is the total of toxicological agents impact. Similarly, for individual etiological agents: $RPN_{Histamine}$ =188, $RPN_{Mycotoxins}$ = 159, $RPN_{Ciguatoxin}$=567, $RPN_{Scombroid}$=866, $RPN_{Chlorine\ compounds}$=2872 and $RPN_{Shell\ Fish}$= 53. Thus, the outbreak illness risk encountered from the previously mentioned etiological agents and based on 20 years trend study could be arranged descending in the following order: Chlorine compounds, Scombroid, Ciguatoxin, Histamine, Mycotoxins and finally shell fish. However, this is a group focus study and the other few or minor scattered cases where not included because the overall toxicity outbreak risk involved other scattered few and minor cases. Nevertheless, the same principle could be applied to them as well.

Conclusion

The present study showed the value of SPC in the outbreak analysis and take it further to a risk evaluation. However, the current risk has no cut-off value or specific limits to determine the present risk from each outbreak case. But, it provides a milestone for further development and improvement to use the full potential of the huge dynamic data available from the internet to guide regulatory bodies in the country for actions to monitor and control outbreaks before a true excursions would occur. The same concept could be applied to other healthcare issue records provided suitable statistical tools were used.

Acknowledgments

None.

Conflicts of interests

Authors declare that there is no conflict of interest.

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