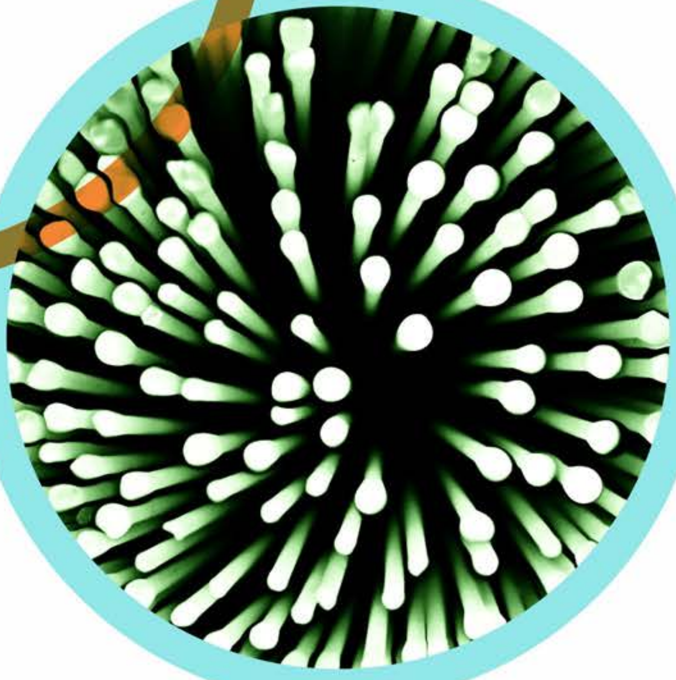

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Perspective

Monitoring of *Cryptosporidium* spp. Outbreaks Using Statistical Process Control Tools and Quantitative Risk Analysis Based on NORS Long-term Trending

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INTRODUCTION

Microbial outbreaks constitute a constant threat to human health and even life in extreme cases. In addition, the epidemics and pandemic diseases are devastating for any country economically. Accordingly, developed nations have established rigorous monitoring and control systems to contain outbreak events and their consequences[1]. As an example, National Outbreak Recording System (NORS) database provides comprehensive records of different types of outbreaks in the USA from which useful patterns and trends could be analyzed for different types of outbreaks[2]. Data processing and analysis using statistical process control (SPC) tools provide insight into outbreak properties and behavior. In addition, they might deliver a simple yet important mean to assess the hazard from specific outbreaks events quantitatively using control charts[3,4]. Despite the usefulness of SPC methodologies, they are still underestimated and uncommon in the field of outbreaks studies although they could provide unique view and interpretation for the monitored diseases and epidemics.

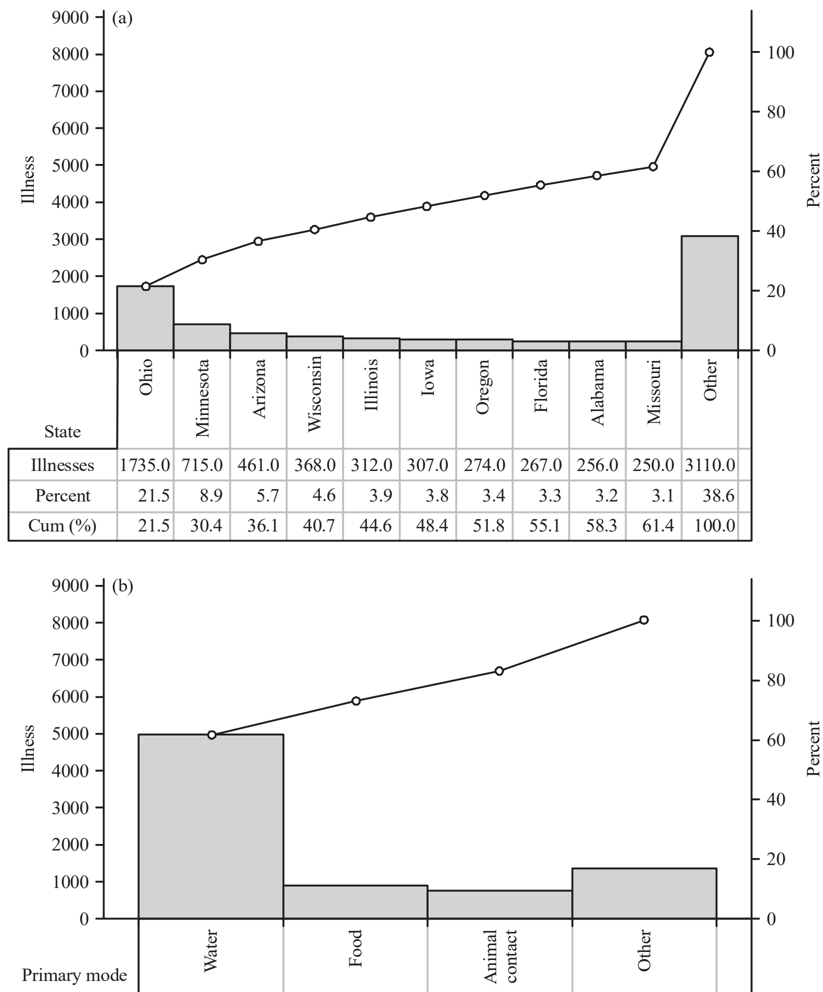
One of the microbial outbreaks that have been recorded and traced is *Cryptosporidium* spp. which causes cryptosporidiosis a gastrointestinal disease with or without respiratory symptoms[5]. This Eimeriorinan protozoan parasite of family Cryptosporidiidae and order Eucoccidiorida belongs to the phylum Apicomplexa, class Conoidasida and subclass Coccidia under Alveolata group of protists (infrakingdom) from Eukaryota domain. It is characterized from other Apicomplexan pathogens by its unique ability to complete its life cycle in a single host and release oocysts without the need of other intermediate vectors such as insects for *Toxoplasma* sp. and *Plasmodium* spp.[5,6]. The SPC study of *Cryptosporidium* spp. outbreaks trend using statistical programs would provide useful information through different perspective.

Long-term monitoring of cryptosporidiosis outbreaks using Pareto analysis shows that the estimated distribution of the etiological agents is as the following: Unidentified species or unknown *Cryptosporidium* spp. (approximately 43.3%), *Cryptosporidium hominis* (21.3%) or *Cryptosporidium parvum* (19.7%) either isolated species alone or associated with other microorganisms or other *Cryptosporidium* spp. (about 15.7%) such as *Escherichia coli* (Shiga toxin-producer and enteropathogenic), *Clostridium* spp., *Cyclospora cayetanensis*, *Giardia* spp., Sapovirus and Norovirus. On the other hand, approximately one quarter of the outbreak records which are estimated to be 471 have data about its locations. Nevertheless, about 12% of the settings of outbreak incidences have not been identified or unknown. However, available dataset indicates that parks (water, amusement, state, mobile home, community/municipal and/or Others), resorts, private residences (house, vacation rental house, home, condo, apartment), community/municipality, child day cares, Long-term care, nursing home, assisted living facility, hotels, motels, lodges, inns, public outdoor areas, Schools/Colleges/Universities, caterers, grocery stores, camps/cabin settings, farms/agricultural Settings and clubs were primary locations for occurrence of *Cryptosporidium* spp. outbreaks.

Less than 20% of the states in the USA are in involved in more than three-fifths of cryptosporidiosis outbreak illnesses with the primary mode of transmission is mainly water, followed by food and finally contact with animals (Fig. 1). However, the mean of transfer in some recorded outbreak incidences could not be identified yet. Despite the possibility of occurrence of cryptosporidiosis outbreaks through the year, more than 60% of incidences occur in the summer periods followed by autumn seasons. The general trend line of the illnesses tends to increase with time since more than 84% of the outbreak sickness cases spotted between years 2011-2017. This could be illustrated in Fig. 2 where a three-dimensional plot shows chronological centering of the reported outbreak illnesses.

Table 1 shows statistical analysis of the disease distribution of illness, hospitalization and death cases. Mortality from cryptosporidiosis infections are very rare phenomena and hospitalization events are low in magnitude if compared with the overall affected individuals by the exposure to the pathogen. In the same line, Fig. 3 demonstrates the distribution of the cases of the outbreak which clearly does not follow Gaussian distribution but may be close to (but not necessarily follow) what is called Log-normal or Weibull pattern of distribution which was observed in other outbreaks analysis study in USA[7]. In order to visualize the pattern, trend and properties of the observed outbreaks, Shewhart charts deliver indispensable analysis for the inspection characteristics in terms of the general tendency, the upper threshold and the out-of-control or abnormal excursions in the illnesses numbers in the trended outbreaks. These parameters could yield data required for the assessment of the health hazard quantitatively from the analyzed outbreaks.

In Fig. 4, testing for data distribution of illnesses per outbreak validity using SPC program was conducted as a diagnostic test which has lead to the construction of Laney attribute chart then variable process-behavior Individual-Moving Range (I-MR) chart was constructed that



State	Ohio	Minnesota	Arizona	Wisconsin	Illinois	Iowa	Oregon	Florida	Alabama	Missouri	Other
Illnesses	1735.0	715.0	461.0	368.0	312.0	307.0	274.0	267.0	256.0	250.0	3110.0
Percent	21.5	8.9	5.7	4.6	3.9	3.8	3.4	3.3	3.2	3.1	38.6
Cum (%)	21.5	30.4	36.1	40.7	44.6	48.4	51.8	55.1	58.3	61.4	100.0

Primary mode	Water	Food	Animal contact	Other
Illnesses	4999.0	887.0	788.0	1381.0
Percent	62.1	11.0	9.8	17.1
Cum (%)	62.1	73.1	82.9	100.0

Fig. 1(a-b): Pareto diagram showing the (a) Major states and (b) Modes of transmission involved in *Cryptosporidium* spp. illness outbreaks from 1998-2017

Graph generated using Minitab version 17 from NORS database

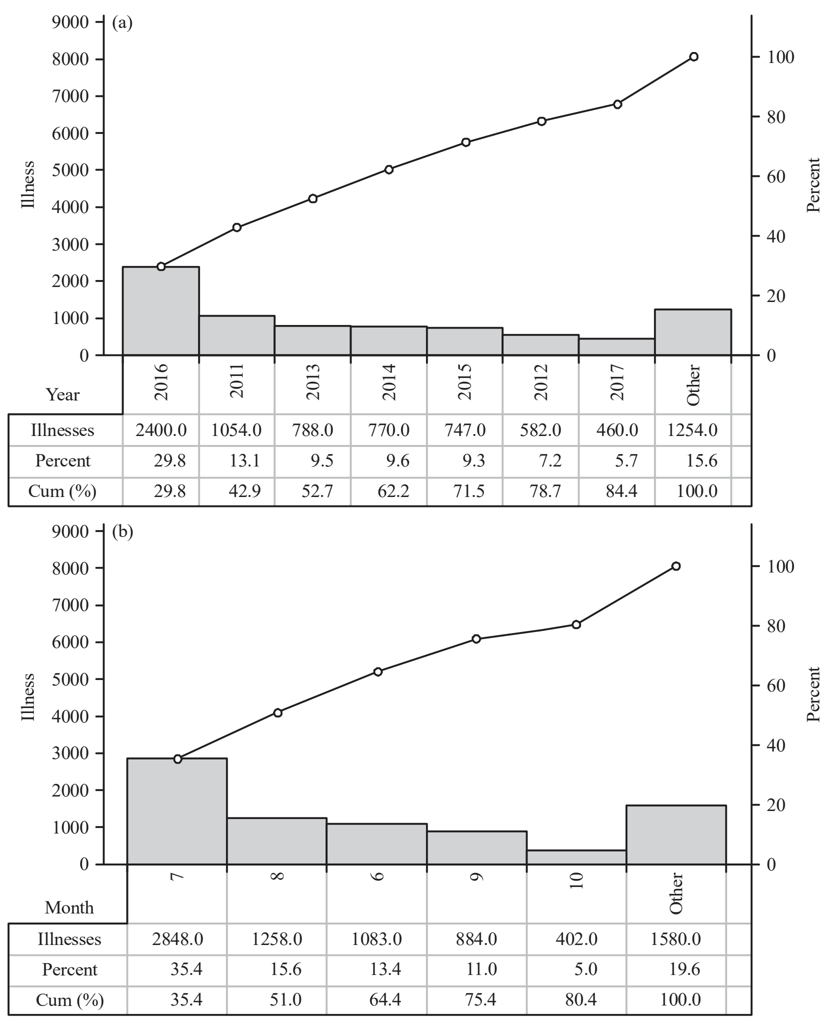
Table 1: Column statistics showing analysis of *Cryptosporidium* spp. outbreaks illnesses in USA during 20 years

Descriptive statistics	Illnesses	Hospitalizations	Deaths
Number of recorded points	462.000	454.000	455.000
Minimum	2.000	0.000	0.000
One fourth Centile	3.000	0.000	0.000
Median	6.000	0.000	0.000
Three quarter Centile	13.000	1.000	0.000
Maximum	638.000	52.000	1.000
One tenth centile	2.000	0.000	0.000
Nine tenth centile	33.000	1.000	0.000
Average	17.440	0.6784	0.002198
Standard deviation	44.960	3.279	0.04688
Standard error of mean	2.092	0.1539	0.002198
Lower 95% confidence interval of mean	13.320	0.3760	-0.002121
Upper 95% confidence interval of mean	21.550	0.9809	0.006517
Lower 95% confidence interval of median	5.000	0.0000	0.00
Upper 95% confidence interval of median	7.000	0.0000	0.00

Table 1: Continue

Descriptive statistics	Illnesses	Hospitalizations	Deaths
D'Agostino and Pearson omnibus normality test			
K2	719.0	855.8	1107
p-value	<0.0001	<0.0001	<0.0001
Passed normality test (α = 0.05)?	No	No	No
p-value summary	****	****	****
Shapiro-Wilk normality test			
W	0.3113	0.1683	0.02281
p-value	<0.0001	<0.0001	<0.0001
Passed normality test (α = 0.05)?	No	No	No
p-value summary	****	****	****
Kolmogorov-Smirnov (KS) normality test			
KS distance	0.3657	0.4181	0.5165
p-value	<0.0001	<0.0001	<0.0001
Passed normality test (α = 0.05)?	No	No	No
p-value summary	****	****	****
Coefficient of variation (CV%)	257.88	483.36	2133.07
Geometric mean	7.488	Not applicable	
Lower 95% confidence interval of geo. mean	6.781	Not applicable	
Upper 95% confidence interval of geo. mean	8.269	Not applicable	
Skewness	8.651	12.40	21.33
Kurtosis	99.93	174.2	455.0
Sum	8055	308.0	1.000

Results generated using GraphPad Prism version 6.01 from Windows from NORS database. ****p≤ 0.0001



Year	2016	2011	2013	2014	2015	2012	2017	Other
Illnesses	2400.0	1054.0	788.0	770.0	747.0	582.0	460.0	1254.0
Percent	29.8	13.1	9.5	9.6	9.3	7.2	5.7	15.6
Cum (%)	29.8	42.9	52.7	62.2	71.5	78.7	84.4	100.0

Month	7	8	6	9	10	Other
Illnesses	2848.0	1258.0	1083.0	884.0	402.0	1580.0
Percent	35.4	15.6	13.4	11.0	5.0	19.6
Cum (%)	35.4	51.0	64.4	75.4	80.4	100.0

Fig. 2(a-c): Continue

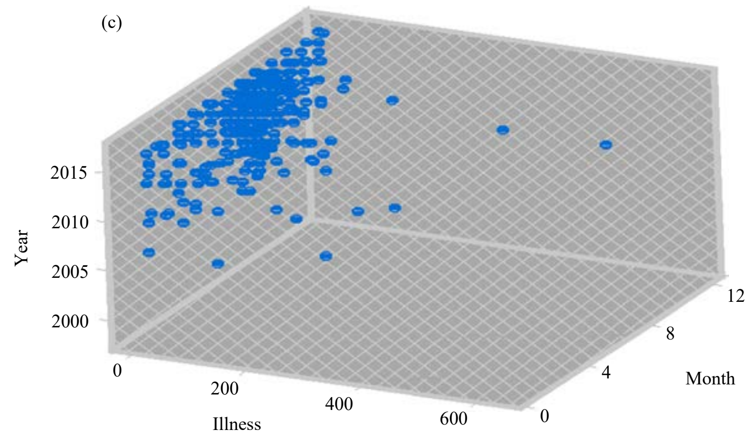


Fig. 2(a-c): Chronological distribution of *Cryptosporidium* spp. outbreaks illnesses (a) Year, (b) Month and (c) Year vs month in USA during 20 years

Graph generated using Minitab version 17 from NORS database

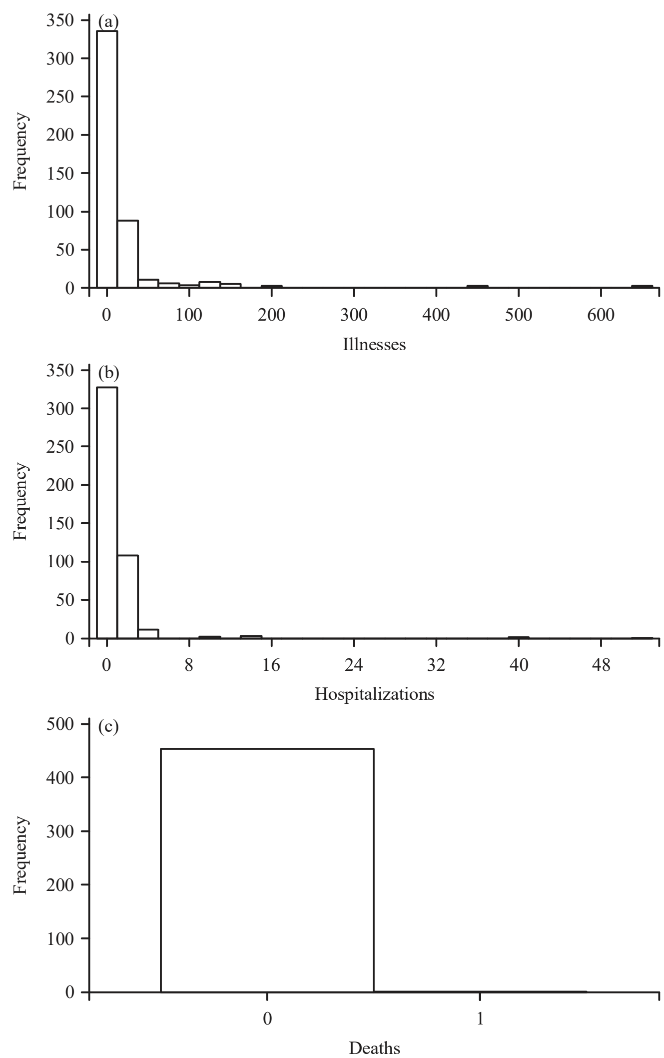


Fig. 3(a-c): Histogram distribution of *Cryptosporidium* spp. outbreaks (a) Illnesses, (b) Hospitalization and (c) Deaths in USA during 20 years

Graph generated using Minitab® version 17.1.0 from NORS database

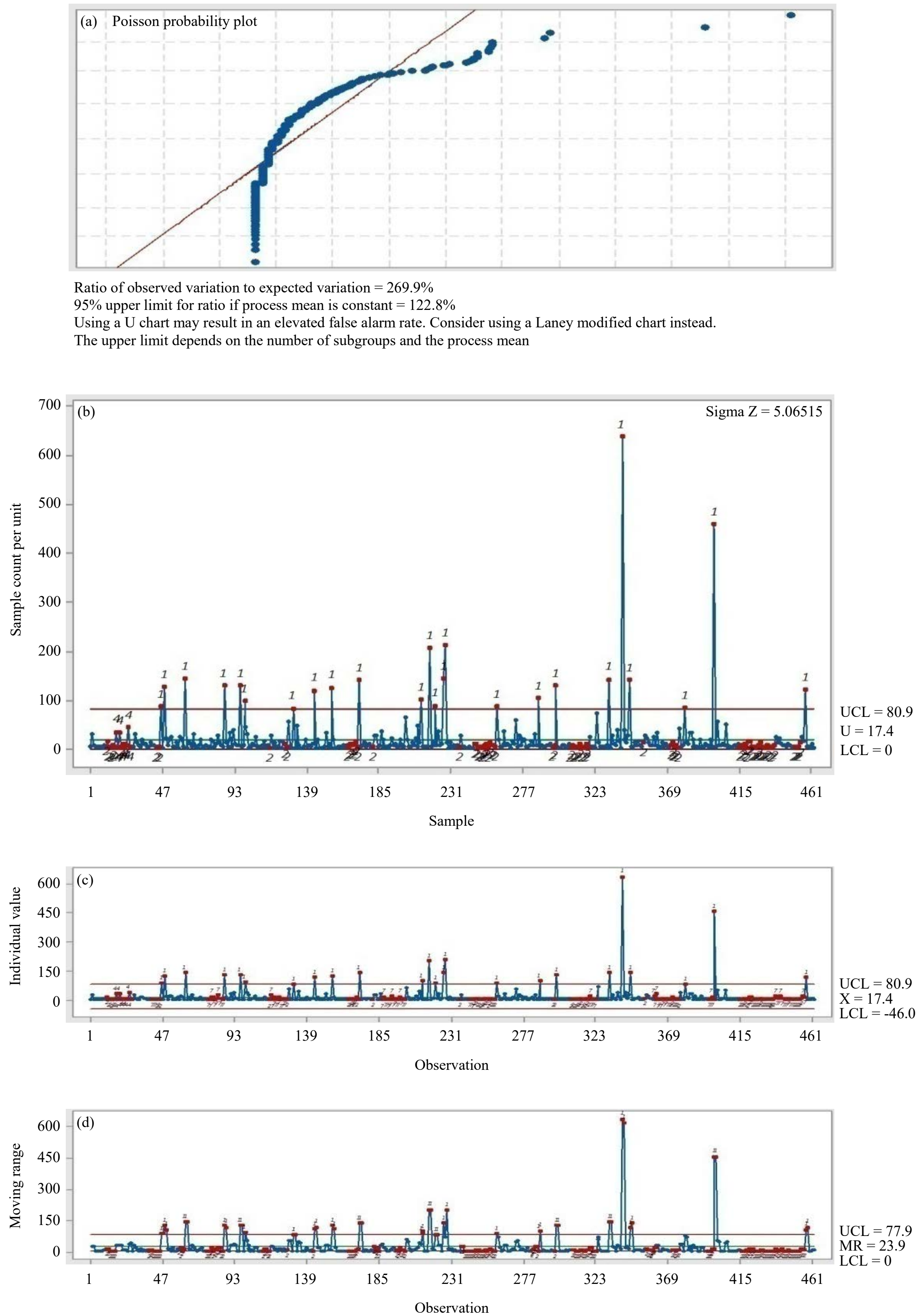


Fig. 4(a-d): Laney-attribute and variable trending charts of *Cryptosporidium* spp. outbreaks illnesses in USA from 1998-2017. Graph generated using Minitab® version 17.1.0 from NORS database showed comparable outcome with the previous modified attribute chart corrected for data dispersion (indicated in graph by σZ value). Thus, this suggests that both types of control charts could be used. Similarly, trending charts could be plotted for hospitalization cases to spot outbreaks with unusual incidences for further investigation and study. The SPC implementation in the monitoring and evaluation of the outbreaks could provide a crucial mean for the study of epidemiological microbial diseases that impact public health and the hazard could be assessed quantitatively.

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