SMALL COUNT DATA AND OUTLIER ANALYSIS:
AN EXPLORATORY STUDY OF PATIENT SAFETY

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ABSTRACT

Small count data presents challenges for analytics and requires significant data inspection. Outliers may become a problem for small count data and are often overlooked. A single outlier may have a strong effect on small count data because of the difficulty in identifying the nature of the outlier. In the healthcare industry, small count data often represent life-threatening incidences, such as rare diseases or “never events” in surgeries. The focus of this research is on data sets that report retained surgical devices. Any single outlier may have an impact on performance. Accurate identification of outliers is essential to healthcare providers. This paper examines two approaches for outlier identification of retained surgical devices data. A proposed method is based on the impact a potential outlier has on the variance of the data. The results of this method are compared to a chi-square distribution to identify potential outliers. The method reported a significantly lower number of outliers in comparison to Tukey fences. The results show that using the variance difference method provides a lucid and conservative approach to outlier identification. In the case of retained surgical devices, outliers may represent variation in the quality of surgical care provided at hospitals. The variance difference method has the potential to help with the accurate representation of small count data.

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INTRODUCTION

There has been increased interest in more accurately modeling count data (Du et al, 2011; Plan 2014). Analyzing count data more accurately can lead to better conclusions in medical care, such as reducing costs, improving patient safety, and increasing quality. There are two problems associated with analyzing count data. The first is to correctly identify the distribution most applicable to the data (Elhai et al, 2008), and second, determine what data points are outliers (Vidmar and Blagus, 2014) that may or may not impact analysis. Many data sets in healthcare are count-based, as they represent the number of incidents or patients. The data sets are challenging to analyze because of the small count, i.e. the numbers reported are neither large nor plentiful (Jones and Spiegelhalter, 2011).

Small count data represent significant problems for analytics in any field, due to the restrictions of using discrete probability distributions. A number of different methods have been proposed to identify outliers or extreme observations yet are susceptible to variations in the data (Miller, 2010; Van Selst and Jolicoeur, 1994). Studies suggest using data inspection techniques such as Benford's law and Zipf's law to detect data anomalies in the social sciences (Cerqueti and Ausloos, 2015; Clippe and Ausloos, 2012). Small count data, however, is problematic for many researchers especially when outliers might be present (Noushek and Shue, 1989). Vives et al., (2006) recommended that researchers become more aware of the characteristics of low count data, as the impact of these characteristics, (e.g. outliers), can affect the results of the methods used for analysis.

In the healthcare industry, small count data represents critical and often life-threatening events. These include for example return to surgery complications, retained surgical devices, fatality after low-risk surgery, and transfusion reaction counts (Jones and Spiegelhalter, 2011; Rose et al., 2006; Elhai et al., 2008). Thus, ensuring proper analysis is key to accurate findings (Mihaylova, 2011). Our research aims to help provide healthcare analysts with a foundation and methodology for analyzing these small counts.

We obtained a data set that contains information on retained surgical device count at various hospitals in NY state. We examined the data to determine the exact distribution of data. Further, using a variance difference method we examine the outliers and posit their possible effects on individual groups within the data set. Finally, we examine group differences using non-parametric tests and provide a rationale for using these tests.

LITERATURE REVIEW

Patient Safety Indicator for Retained Surgical Device

The Centers for Medicare and Medicaid Services (CMS) refers to and includes in their quality rating metrics a Patient Safety Indicator (PSI) for Retained Surgical Device. The program determines penalties and fines given to hospitals. PSIs are a set of indicators providing information on potential in-hospital complications and adverse events following surgeries, procedures, and childbirth. The government includes PSI 05 RSD in this program as a significant preventable healthcare event.

Retained surgical devices (RSD) are foreign objects unintentionally left in a patient after surgery or other procedure. Objects include surgical sponges, broken parts of instruments, stapler components, parts of laparoscopic trocars, guide wires, catheters, needles and instruments (Sentinel Event Alert, 2013). Retained surgical devices (RSD) often result in significant patient harm that involves reoperation, readmission/prolonged hospital stay, sepsis, bowel obstruction, visceral perforation, and death (Gawande et al, 2003; Steelman et al 2018).

The government quality assurance committees, healthcare associations, and advocates refer to retained surgical items as a preventable medical error that should never happen (The National Quality Forum, 2018). Hospitals require highly reliable practices to prevent retained surgical items (Bean 2018). The key causes for retained surgical items include inconsistent or unreliable practices in the operating room and human error during procedures where counts of sponges and instruments were reported as correct (Stawicki et al, 2013). Many other risk factors have been identified that include longer duration of surgery, and safety variances (ASC communication 18; Stawicki et al, 2013), emergency procedures, unplanned change in operation, and body mass index, and manufacturing defects (Stawicki et al 2013; Yildirim, T. et al 2015).

Studies concerning RSD recommend intervention programs (Mehtsun et al., 2013), such as the sponge accounting system, radio frequency detection system (Rupp et al., 2012), surgical instrument count and x-ray of the patient surgical site (Stawicki, 2012), root cause analysis, and mandatory training for new interns (Vannucci et al., 2013). Data sources for these include the National Physician Data Bank, paid malpractice settlements and government reporting. Some suggest an anonymous RSD reporting system is necessary to better track both the incidence and risks associated with this problem (Conlon et al., 2008).

Collecting data for large RSD studies has been difficult due to miscommunication as to when and if the event occurs. The severity of medical and legal implications may prompt inaccurate medical coding or purposeful non-reporting (Bowman, 2013). For example, research indicates that approximately 4,500 to 6,000 surgical item cases occur annually in the U.S (Gluncic et al. 2013), RSD events occur in 1:5500 surgeries (Cima R.R. et al, 2008) and RSDs occur in approximately 1 per 1,000 abdominal operations (Stawicki, 2013). However, the Joint Commission received only 772 voluntary reports of retained surgical items in seven years (Sentinel Event Alert, 2013). This disparity in incidents suggests the need for more studies to determine a policy that may be used to help prevent the risk of RSD.

The problem of outliers in healthcare is a well-noted one especially from a low count, Poisson like distribution. The Brooklyn Law Journal (Greene, 1992) published an article regarding the use of outcome statistics and recognized the issue with chance observations, outliers, and their impact on cases. Further, outliers may impact perceived performance measured by a number of characteristics (Shahian and Normand, 2015). The study and effective identification of outliers may have a significant impact on policies, which leads to better improvements in the health systems and improve outcomes (Chang et al., 2019). Additional research is needed to identify policies, such as strengthening supply chains, and attributes of health systems and governments, such as reduced corruption, that lead to more efficient spending and improvements in intermediate outputs and outcomes of health systems. In a study of provider performance, Shahian et al., 2013 showed that provider performance of observations considered outliers did not significantly differ from the mean. The consequences to providers of incorrectly labeled outliers in measuring performance can be significant, especially with respect to referrals and reimbursements (Bilimoria, et al. 2010).

Outliers

Outlier analysis and identification are important to ascertain observation points that influence assumptions of parametric testing and then managing the outliers to reduce bias on summarized results. Outliers may occur by chance in any distribution, but they often indicate data entry and ensuing measurement error, heavy-tailed distribution or by the presence of a unique population (Leys et al, 2013). When the sample size is small the effect of outliers could be more pronounced (Cousineau and Chartier, 2010).

A number of methods have been proposed to screen for outliers, and many of these methods have been shown to be sensitive to sample size, skew of the distribution, and arbitrary selection of cutoff criterion (Miller, 2010; Van Selst and Jolicoeur, 1994). Van Sels and Jolicoer (1994), developed a number of Monte Carlo simulations and showed how outlier detection and elimination were affected by small sample sizes, irrespective of the method used. This variation in the data from small sample sizes to varying distributions makes outlier detection much more difficult and as such, when measuring performance, it becomes a critical factor to understanding performance data.

In medical literature, outliers have been identified by selecting data points based on various methods. Some of these methods refer to Tukey (i.e., interquartile range analysis), cutoff levels ranging (i.e. e, upper 0.5% to 20% of the distribution), and use of the geometric mean plus standard deviation (Cots et al. 2003; Pirson, et al 2006).

Some studies distinguish observations that are influential in an outlier data set. An influential observation is a type of outlying observation whose exclusion results in a significant change in a function or parameters (Cousineau and Chartier, 2010). Observations that have a significant consequence on statistical results are influential. Approaches to identify influential observations include using measures of standardized differences between regression coefficients when a given observation is included or excluded (Choi, 2009). Cook's distance that summarizes the influence of each observation on the fitted model parameters after deleting each observation from the estimation and measuring the resulting aggregate changes (Indurkhya et al. 2001). A comparison of methods for outlier analysis may help identify influential observations from outlier data points (Orr et al., 1991). Understanding how outliers change with each approach is important in assessing the impact of a particular method on the result and in ascertaining influential observations.

METHODOLOGY

We obtained a dataset from the New York government health website (https://health.data.ny.gov/Health/All-Payer-Patient-Safety-Indicators-PSI-Volume-Mea/ge6u-uxxf/data). The data set titled *“All Payer Patient Safety Indicators (PSI) Volume Measures by Hospital: Beginning 2009”* includes two PSI count data. The two PSI's are, PSI 05, retained surgical item or unretrieved device fragment count, and PSI 16, transfusion reaction count. The data includes reported counts for the years 2009 through 2016.

The downloaded data set was filtered to include only records associated with PSI 05. The number of hospital discharges with a retained surgical item or unretrieved device fragment (secondary diagnosis) among surgical and medical patients ages 18 years and older or obstetric patients (www.qualityindicators.ahrq.gov). This count does not include patients returning to surgery that had not been discharged, as the primary reason for the return, or those patients who are unaware of the issue.

For this study, only the last three years, 2014-2016, of data were analyzed. Our choice of limiting the analysis is based on the effort and investment in quality programs, and safety processes to reduce the number of RSI cases over the last few years. We determined that the period of 2014 - 2016 is a valid time frame for assessing the current state of the problem. This research only clarifies outliers and influential cases for further analysis and does not explore the reduction rates over time. The shorter time frame also represents a decision on the part of the researchers to account for recent dramatic changes in surgical techniques and equipment with the increase in laparoscopic and robotic surgery. Table 1 shows the number of incidents by region in NYS for each of the three years.

Year	BX	CA	CNY	FLK	HVA	KC	LI	MH	SIQ	WNY	Total
2014	3	6	12	5	4	4	9	11	2	7	63
2015	5	5	8	2	4	4	9	9	0	11	57
2016	5	5	9	6	2	7	6	9	1	7	55

BX - Bronx
CA - Capital / Albany
FLK - Finger Lakes
HVA - Hudson Valley
LI - Long Island
MH - Manhattan
WNY - Western NY

CNY - Central NY KC - Kings County SIQ - Staten Island / Queens

Table 1: Number of Incidents by Region in NY

ANALYSIS

Distribution Identification

One goal was to identify the possible distribution of the data at the individual region level. Each observation represents the number of incidents that occurred in a given hospital, and these observations are then grouped by regions. Since the data represents count data, our first presumption, is that the data follows a Poisson Family Distribution, i.e. Poisson or Negative Binomial. Since the data contains no zero's we further posit that the data must come from a Zero Truncated Poisson (Cohen, 1954), or Zero Truncated Negative Binomial Distribution (Sampford, 1955). The histograms in Figure 1, show the distribution of the entire data set along with the theoretical distribution for the ZTP and ZTNB distributions.

Figure 1: Observed Versus Theoretical Distributions (ZTP, ZNB)

For this pilot set of data, we have a mean higher than the variance ($\mu = 1.5$, $\sigma^2 = .92$). We first try to accurately determine the distribution of the data with the ultimate goal of the analysis to determine if a single incident within the data set should be included or removed as an outlier. Using the data available, we analyzed the incidents and compared them to the described theoretical distributions (Table 2).

Count	**Observed**	**E[X] - ZTP**	**E[X] -ZTNB**
1	96 (.744)	86 (.667)	88 (.682)
2	24 (.186)	37 (.287)	28 (.217)
3	5 (.038)	4 (.031)	10 (.077)
4	4 (.031)	2 (.015)	3 (.233)
χ^2		4.717 (p=.85)	4.082 (p=.90)

Table 2: Table of Observed Probabilities and Theoretical Probabilities

Examining the χ2 against the actual values, the zero-truncated negative binomial distribution appears to the best fit, since it has the lowest significant χ2 value. One concern that needs to be more closely examined is the possibility for underdispersion, i.e. mean greater than the variance. For this paper, we did not run a test for the dispersion to see if there is equidispersion, underdispersion, or overdispersion; however, Cameron and Trevedi (1999) suggest such a test. Underdispersion may be caused by some misinterpretation or failure in the population, which may be due to variability within the data, sampling issues, clustered, the structure of the population, and small sample sizes (Kokonenji, 2014). Researchers and analysts need to be concerned about dispersion issues and identify the correct distributions for their analysis, otherwise, they could be prone to misinterpretation of the model results or incorrect estimations of the parameters (Kokonenji, 2014). The Zero-Truncated Negative Binomial is an appropriate distribution in healthcare analytics and has been used in mental health statistics for patient visits (Eihai, et al., 2008), race and stroke readmission (Kennedy, 2005), and outliers in patient outcomes (Stylianou et al., 2017).

Identifying outliers

Next, we seek to identify outliers in the dataset approach to the issue of outliers. Outliers are observations considered to be very different or deviate from other observations significantly. Similar to the issues raised above regarding dispersion, outliers can also cause misleading analysis or improper predictions (Pelaez et al., 2018). Outliers can come about from simply a difference between the other observations or signal that a particular observation or observations were the result of something different, from which the data was collected (Grubbs, 1950; Hawkins, 1980). Identifying and proper removal of outliers will yield different results in most cases and are thus indicative of more appropriate results (Grubbs, 1950).

Using the variance difference method (Pelaez et al., 2018), we aim to identify the difference in results obtained by remove outliers from the healthcare dataset. The primary objective is to narrow outliers identified using the inner fence method, which may be too conservative, and the outer fence methods. The negative binomial distribution is small count data distribution with differences in observations around 1 or 2. In the case of the current data, the range of observations is from one to four. The proposed method measures the difference in variance attributed to the removal of high right-side outliers. The sample variance of a random variable, under a normal distribution, follows a Chi-squared distribution, Cochran's theorem (1934). Further, the chi-squared distribution is a reasonable approximation for the index of dispersion (Loukas and Kemp, 1986). These two are combined to calculate the right tail of the chi-squared distribution, thereby, enabling the identification of which variances are beyond a critical point of the Chi-Square.

The current data set contained, 129 observations, the variance for the data set was .92 (σ^2 =.92). The variance of the data was recalculated through an iterative process, whereby each observation is removed and the difference in the variance is recorded. The resulting dataset is compared to a Chi-Square distribution with degrees of freedom equal to the count of the differences, see Table 3. The possible outliers are then compared to this distribution and the number of outliers removed whose differences are greater than the calculated Chi-square statistic.

Threshold	**.98**	**.985**	**.99**
$\chi2$	.000158	.00148	.013
Outlier Range	1-4	1-4	3-4
# of Possible Outliers	129	129	9

Table 3: Variance Difference across all regions

Table 3 contains the results of prospective outlier values for the entire dataset. At 99% $\chi2$ level, we remove 9 outliers, i.e. with counts of 3 and 4, while the Tukey method removes only 4 observations with counts of 4, i.e. Tukey inner fence method. Since our goal is to identify possible outliers for each region, we focus on outlier removal within each region. The smaller sample size reduces the analysis to under 21 for each of the hospitals. Table 4 shows the outliers that are removed for each of the regions using the variance differences.

The boxplot in Figure 2 shows the range of incidents for hospitals in a given region. The dots are considered outliers according to the Tukey Method.

Figure 2: Counts of incidents by Region

Region	**Total Incidents**	**97%**	**98%**	**99%**	**Tukey Outliers**
Bronx	8	0	0	0	0
Capital/Adiron	12	2	0	0	2
Central NY	21	1	0	0	5
Finger Lakes	8	0	0	0	0
Hudson Valley	10	0	0	0	0
Kings	12	0	0	0	0
Long Island	19	5 (.975)	0	0	0
Manhattan	19	0	0	0	1
SI/Queens	3	0	0	0	0
Western NY	17	0	0	0	4
Total	**129**	**8**	**0**	**0**	**12**

Table 4: Outliers identified by method (Variance Difference and Tukey)

Table 4 provides the number of possible outliers at the various levels of the Chi-Square distributions. The last column contains the number of outliers identified using the Tukey, inner fence, method. It can be shown from the table above that the number of outliers identified by the proposed method matches in 6 cases. In only one case did the method, propose additional outliers, when the Tukey method did not, otherwise the method was more conservative in the outlier estimation. Overall, for each region, the Tukey method identified 12 outliers, while using our proposed method only 8 outliers were identified, 5 of which came from one region and need further investigation.

In the instances where the variance difference method suggests not removing outliers, while the Tukey method does, more analysis on these observations may be warranted. As such, quality programs and development of cost metrics based on small count data set may benefit from comparing various outlier approaches.

Analyzing outlier methods and results may help healthcare administrators to better allocate limited resources for program investments. Programs in quality assurance, disease management and/or mistake-proofing efforts may require a direction focused through sample analysis as well as outlier analysis.

In the case of retained surgical devices (RSD) identifying outliers in the upper tail from sample data may uncover variation in hospitals. This study identifies five outliers in the Long Island region. The outliers may identify differences in hospitals as having different demographic characteristics (i.e., size, case complexity, age of medical staff, trauma center) from other hospitals within the same region. The outliers, therefore, may become influential events and direct quality assurance committees to allocate resources for improved patient safety,

CONCLUSION

The data observations included in this study are those reported to NY state patient safety. Medical providers might fear adverse consequences as a result of "full disclosure" with potentially, public records such as discharge abstracts. Therefore, incomplete reporting is an issue when examining the results for the accuracy of count data.

Small count data is vulnerable to the removal of outliers (Cousineau and Chartier, 2010). Generally, statistical analysis removes outliers based on the interquartile range and is independent of the parameters of the distribution. In small count data sets, even if n is large, this may not perform adequately.

The variance difference method identified the Long Island region as including 5 outliers. The Tukey method has zero outliers for Long Island. It may be valuable to include these outliers in a bin for count and analysis. The bin for these outliers may be considered influential events. Although a low count of 2 does not logically indicate a single outlier or influential event the variance difference method looks at a single observation, at a time. This group of two counts may indicate a special circumstance of the distribution. More research is required at the level of observation point to help assess the value of the difference squared at various levels and enhance the current method based on the chi-squared value.

This study reports only on hospitals in New York state. Future studies might apply the variance difference method and compare the outlier analysis to a different study of hospitals in the United States. In addition, many countries account for patient safety data either as incident counts or as rate value. The methodology presented in this study may be developed and extended for rate data.

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