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METHODOLOGICAL NOTES

Using Infant Mortality Data to Improve Maternal and Child Health Programs: An Application of Statistical Process Control Techniques for Rare Events

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Abstract
Introduction The infant mortality rate (IMR) in the United States remains higher than most developed countries. To understand this public health issue and support state public health departments in displaying and analyzing data in ways that support learning, states participating in the Collaborative Improvement and Innovation Network to Reduce Infant Mortality (IM CoIIN) created statistical process control (SPC) charts for rare events. *Methods* State vital records data on live births and infant deaths was used to create U, T and G charts for Kansas and Alaska, two states participating in the IM CoIIN who sought methods to more effectively analyze IMR for subsets of their populations with infrequent number of deaths. The IMR and the number of days and number of births between infant deaths was charted for Kansas Non-Hispanic black population and six Alaska regions for the time periods 2013–2016 and 2011–2016, respectively. Established empirical patterns indicated points of special cause variation. *Results* The T and G charts for Kansas and G charts for Alaska depict points outside the upper control limit. These points indicate special cause variation and an increased number of days and/or births between deaths at these time periods. *Discussion* T and G charts offer value in examining rare events, and indicate special causes not detectable by U charts or other more traditional analytic methods. When small numbers make traditional analysis challenging, SPC has potential in the MCH field to better understand potential drivers of improvements in rare outcomes, inform decision making and take interventions to scale.

Keywords Infant mortality · Statistical process control (SPC) · Rare events · Quality improvement

Significance

The United States has one of the highest infant mortality rates of developed countries. Quality improvement efforts to reduce infant mortality, and particularly to reduce disparities, are hampered by current methods for reporting and analyzing infant mortality data. These methods pose challenges to using data in real time to evaluate the impact of programs and inform decision making. This paper demonstrates how application of statistical process control methods to infant mortality data can enhance data analysis and quality improvement efforts, particularly for rare events.

Introduction

The infant mortality rate (IMR) in the United States remains higher than most developed countries, (Macdorman and Mathews 2014; Organisation for Economic Co-operation

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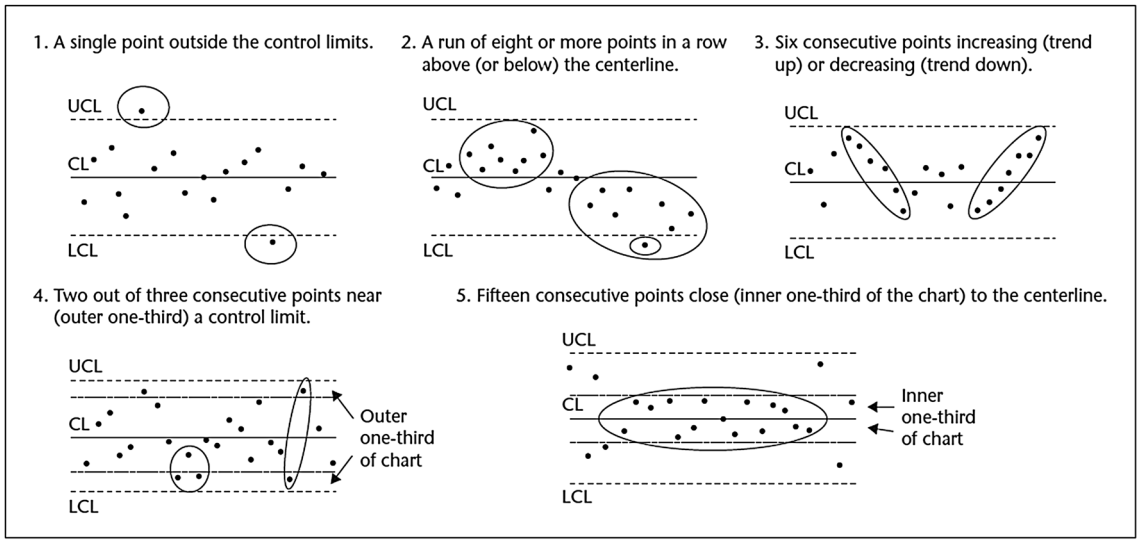

Fig. 1 Rules signaling special cause variation (Provost and Murray 2011). Permission from the author

and Development 2014) and disparities persist (Mathews and Driscoll 2017). To address the high IMR, the Health Resources and Services Administration Maternal and Child Health Bureau funded a national Collaborative Improvement and Innovation Network to Reduce Infant Mortality (IM CoIIN) in 2014 (Grant Number UF3MC26524). Led by the National Institute for Children's Health Quality (NICHQ), this initiative brought together 51 states and jurisdictions with the goal of improving birth outcomes.

The IM CoIIN sought to serve as an example that State Vital Records data, collected and interpreted frequently, could be leveraged for undertaking change efforts. Participating states were supported in collecting and displaying close to real-time provisional quarterly vital records data to assess the impact of tested interventions on IMR. Timely data, displayed with methods that facilitate learning from variation in small increments over time, has the potential to enhance state efforts to track changes, refine program activities and accelerate improvement.

However, while surveillance of IMR is common, this data-driven approach to learning is not ubiquitous. Reporting and analyses of infant mortality data from state Vital Records Offices (VROs) and the National Center for Health Statistics often lag multiple years (Kochanek et al. 2016). Additionally, infant mortality is a relatively rare event and researchers commonly utilize two distinct methods to make statistically robust comparisons (1) 3–5 year rolling averages and (2) comparing two distinct time periods spanning a decade or more (Brown Speights et al. 2017; Lau et al. 2013; Macdorman et al. 2013). Furthermore, aggregation is employed to meet confidentiality and legal requirements. Analytical approaches that leverage retrospective, aggregated and suppressed data hamper learning from variation and delay decision making and progress in improving the IMR.

Statistical process control (SPC) offers a framework for Maternal and Child Health (MCH) programs to analyze real-time infant mortality data and enhance improvement efforts. Introduced in the late 1920s, Walter Shewart distinguished between "common cause variation," or variability inherent in a process that remains stable over time and "special cause variation," or variability that results from change or non-natural circumstances (Benneyan et al. 2003; Shewhart 1980). To differentiate these forms of variation, SPC uses control charts to plot measurements, usually in chronological order, along with three horizontal lines: a centerline (mean) as well as lower (LCL) and upper control limits (UCL), which are set to three sigma (an estimate of the common cause variation) from the centerline. Several types of control charts exist, each with a calculation of the sigma value and control limits based on statistical formulas appropriate for the data being analyzed (Mohammed 2004). Geometric (G-chart) and time-between (T-chart) SPC charts that plot the opportunities or time between events of interest, are used to analyze rare events data. T and G charts are particularly useful for subgroup analyses, such as looking at IMR by race or region. Empirical-based patterns are used to indicate special cause variation (Fig. 1) (Provost and Murray 2011).

As SPC is sensitive to change and specifically intended as a management tool to learn from variation, the IM CoIIN leveraged SPC methods to support public health departments to display and analyze data in ways that support learning. Here we present IMR data from two states participating in IM CoIIN, using three types of SPC charts (a U-chart, a common SPC chart, as well as T- and G-charts, intended for rare events). Kansas and Alaska sought methods to more

Table 1 Summary of U, T and G SPC charts for infant mortality data

Chart	x-axis	y-axis	Distribution used to calculate centerline and limits	Direction of improvement	Considerations/limitations
U chart	Time in quarters	Infant mortality rate per 1000 live births	Poisson	Down indicates improvement in infant mortality. Use LCL to quickly detect improvement	For rare events, there is often no LCL which limits detection of improvement
T chart	Date of an infant death	The number of days between consecutive infant deaths	Exponential	Up indicates improvement in infant mortality. Use UCL to quickly detect improvement	Not as sensitive as G chart for rare events. May not have LCL. Unlike the U chart where users rely on the LCL to indicate improvement, the UCL indicates improvement on T and G charts
G chart	Date of an infant death	The number of births between consecutive infant deaths	Geometric	Up indicates improvement in infant mortality. Use UCL to quickly detect improvement	Because of the skewed nature of the geometric distribution, there is no LCL on a G chart, which limits detection of worsening. The G chart is more sensitive than the T chart but requires both time and opportunities between events

effectively analyze IMR for subsets of their populations where infrequent infant deaths made understanding trends with traditional statistical models challenging. Both states had strong relationships with their VROs and data agreements in place, facilitating access to the necessary data. Use of SPC is a novel approach in the MCH field, as to our knowledge, the field has not yet published infant mortality data using these techniques at the state level.

Methods

To monitor progress over time and facilitate learning from infant mortality reduction efforts in specific subsets of populations, U, T and G charts were used to analyze infant mortality data in Kansas and Alaska for the time periods 2013–2016 and 2011–2016, respectively. The years 2011 and 2013 were selected as starting points to ensure sufficient data points to accurately calculate limits for each chart ($k > 12$). All charts were created by IM CoIIN Improvement Advisors using QI Charts, a Microsoft Excel add-in (Process Improvement Products 2017). Formulas for the calculation of centerlines and UCL and LCL can be found in The Healthcare Data Guide. Established rules (Fig. 1) were used to identify special cause variation, and a summary of the key characteristics of each chart can be found in Table 1 (Provost and Murray 2011). Calls were held with state teams to review the methods, results and ways states could continue to utilize these methods. The results described below are based on secondary analysis of vital records surveillance, not patient, data, provided by the Kansas Department of Health and Environment Office of Vital Statistics and Alaska Section of Health Analytics and Vital Records.

U Charts

Live births and infant deaths occurring quarterly for the Kansas non-Hispanic black (NHB) population and two Alaska regions were used to calculate the IMR per 1000 live births. As infant mortality is a count of deaths per standard area of opportunity (1000 live births), we constructed U charts, with time in quarters on the *x*-axis and the IMR per 1000 live births on the *y*-axis. Sigma formulas for the Poisson distribution were used to calculate the centerline and control limits (Provost and Murray 2011).

A rare event is defined here as any measure that can be expected to be zero in the time periods under study. Rare events, such as infant deaths, can make U charts ineffective because they result in zeros plotted for many time periods and a LCL calculated as less than zero and, thus, not on the chart. In the case of infant mortality, the LCL on U charts allows for rapid detection of improvement. For example, in the Alaska Alpine Region there were no infant deaths in eleven of the reporting quarters seen on the U chart (Fig. 3a). For U charts, the combination of average rate and the opportunity size (number of live births here) creates the expectation for zeros in any time period. For example, if the average rate is 5/1000, then a subgroup size of 1800 births would be required to have a lower limit, while an average subgroup size less than 280 would lead to an ineffective chart with too many zeros.

T and G Charts

To overcome these limitations, and allow for greater detection of improvement, we constructed T and G charts. Dates of infant deaths and number of births were used to generate T and G charts, respectively. For deaths that occurred on the same day, we allocated half of the average births per day to each death. While the actual date of an infant death was used in calculations, we marked the *x*-axis with the month and year of the infant death to ensure confidentiality. The *x*-axis was formatted uniformly (does not convey actual time). The number of days (for T chart) or number of births (for G chart) between consecutive deaths was plotted on the *y*-axis. The centerline and control limits were calculated using established formulas for the exponential (T chart) and geometric (G chart) distributions.

Results

Kansas

Figure 2a shows the quarterly NHB IMR in Kansas from 2013 to 2016 plotted using a U-chart. The centerline of 12.8 represents the average IMR per 1000 births from Q1 2013–Q4 2016. Quarter to quarter, the UCL varies from 25.5 to 26.7 due to varying subgroup size. The calculation of the LCL is below zero and thus does not exist for this chart. While there is year-to-year fluctuation, none of the special cause rules are seen, indicating common cause variation in the measure. The centerlines for the T and G charts (Fig. 2b, c) are 7.2 and 54.1, respectively, indicating an average of 7 days and 54 births between deaths of a NHB infant. A special cause signal is seen in both the T and G charts in December 2014. The data points for this time point exceed the UCL with 85 days (T chart) and 608 births (G chart) between deaths. Two additional points outside the UCL are seen in the G chart in July 2015 and May 2016 with 340 births and 350 births, respectively. These special cause signals indicate a possible change in the system with an increased number of days and/or births between deaths seen during these time periods.

Alaska

Figure 3 shows infant mortality data in two regions[1] in Alaska from 2011 to 2016, plotted using U and G charts. T charts are not displayed, as they did not show special causes. There is no LCL on the U charts (Fig. 3a, c) and several time points have zeros plotted. The Alpine Region U chart (Fig. 3a) shows a point outside the UCL in Q1 2015, with an IMR of 24.0 per 1000 indicating an increase in infant mortality during this quarter. The centerlines for the Alpine and Boreal Region G charts are 152.2 and 128.2, respectively, indicating an average of 152 and 128 births between infant deaths in those regions (Fig. 3b, d). The Boreal Region G chart shows one point outside the UCL in August 2014 with 1286 births since the previous death. The Alpine Region G chart shows one special cause signal in June 2012 with 1304 births, exceeding the UCL.

Discussion

Using state and regional infant mortality data, we demonstrated that SPC charts have the potential to aid MCH practitioners in interpreting and learning from data and highlight the value of utilizing T and G charts to better understand rare events. SPC charts offer several advantages over other commonly used methods for analysis, including the opportunity to create continuously updated charts to monitor IMR and improvement efforts closer to real-time. Additionally, while other statistical methods seek to smooth out variation across time, to account for seasonal variation and natural random variation, SPC charts enhance understanding by distinguishing between common and special cause variation using statistically-based rules.

This theory of variation, along with the use of SPC charts can provide a basis for informed action for programs seeking to address rare, but significant outcomes, such as infant mortality. State and local health departments can leverage T and G charts to monitor and learn from variation in IMR not apparent using traditional statistical methods or other SPC charts. For example, the G charts from Kansas and Alaska indicate special causes that were not detectable with the U chart, namely increases in the number of births between deaths for specific time periods. While these signals were identified retrospectively, prospective and ongoing use of these methods can provide an opportunity for states to learn what changes are driving the system change in real-time. Those changes can then be replicated elsewhere to spread improvement. For example, Kansas may want to consider changes happening prior to December 2014 that could have resulted in an increase in the number of days and births between infant deaths and make those changes a reliable part of the system to improve IMR. Alaska is sharing the G charts at their Maternal Child Death Review Annual Meeting, with the goal of using these methods to better understand and provide recommendations to prevent future deaths. T and G charts can also be used to assess the impact of

[1] Regional names have been altered to suppress identifying information.

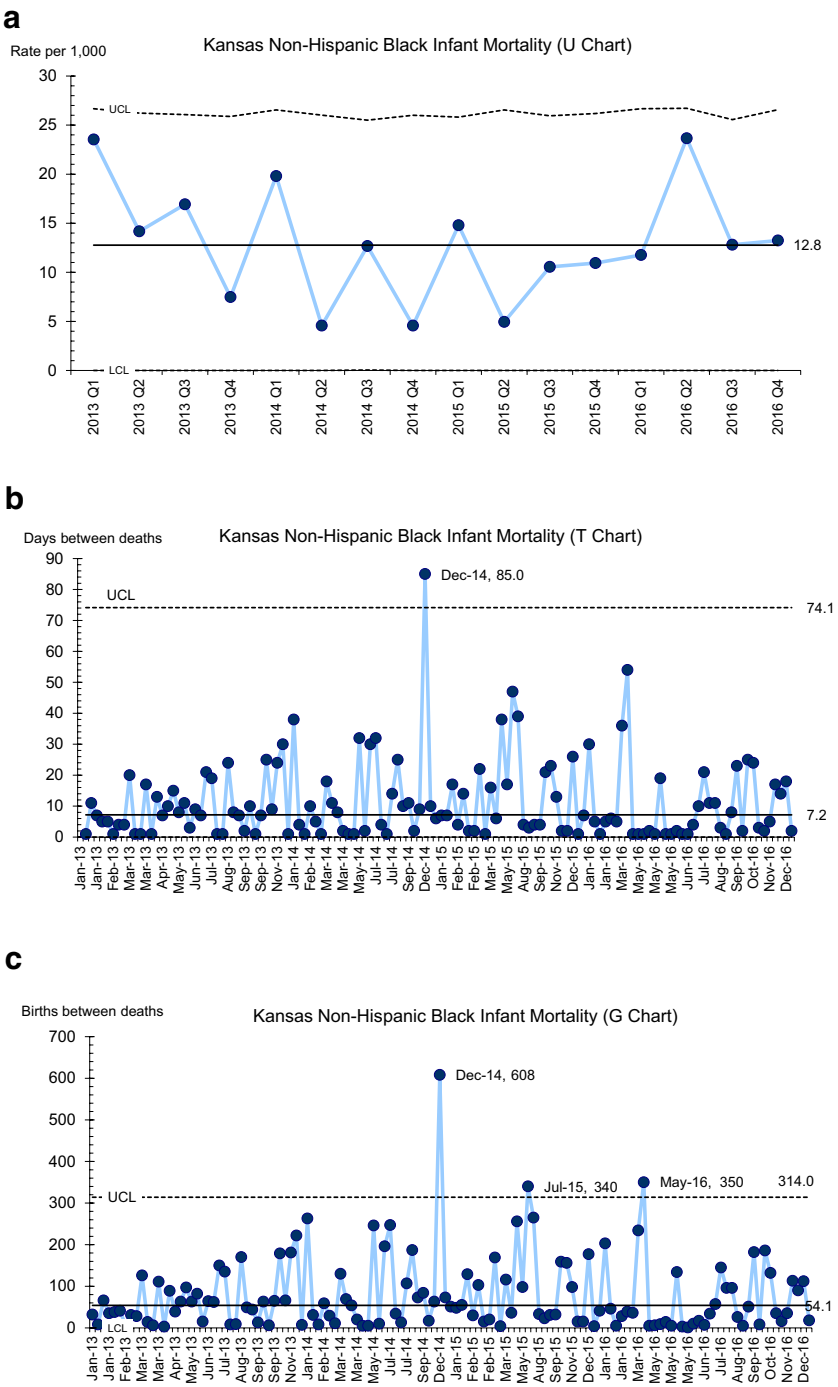

Fig. 2 Kansas Non-Hispanic Black infant mortality U chart (**a**), T chart (**b**) and G chart (**c**)

new programs or services, thereby avoiding investment in changes that are not producing measurable impact.

Furthermore, in contrast to other statistical methods that falter with small subsamples, the use of T and G charts provides a robust method to learn from data from racial or regional subgroups, where there might not be an infant death in each reporting period. These methods provide an opportunity to enhance learning about the impact of programs and services on these subpopulations to support targeted interventions. In reviewing the G charts, Alaska identified that the time frames for improvement varied between regions and that they needed to better understand what local changes were happening at those specific times. These insights would not have been possible with aggregated data. Finally, these charts allow the review and interpretation of data at the time of each event, improving the timeliness of data analysis.

Despite the numerous benefits of SPC charts, the following limitations should be considered before applying these

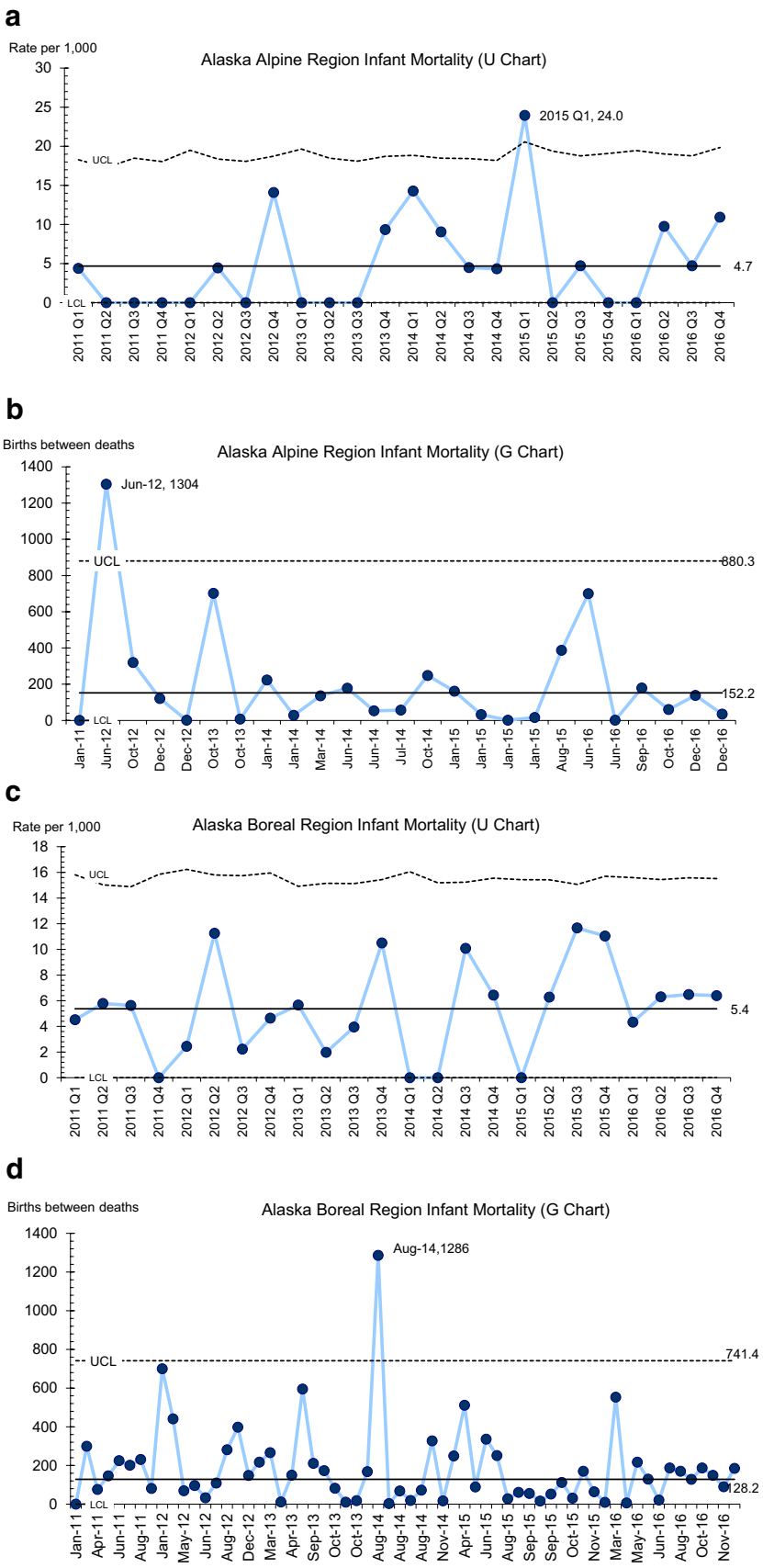

Fig. 3 Alaska Alpine Region infant mortality U chart (**a**) and G chart (**b**) and Alaska Boreal. Region infant mortality U chart (**c**) and G chart (**d**)

methods. The G chart (and often the T chart) do not have a LCL, which reduces their utility in detecting the worsening of a condition. However, use of the T or G chart with a U chart, helps ensure that both improvements and increases in mortality are detected. For example, the Alaska Alpine U chart revealed worsening of infant mortality during Q1 2015; due to lack of a LCL, examination of these same data with the G chart did not detect this increase in IMR. In addition, the use of SPC charts in MCH settings may not be familiar to all users; education and guidance to correctly apply these charts is required. Additionally, while not unique to SPC, legal restrictions on the use of vital events data and lack of timely access to data may limit application of these methods for learning. For example, while quarterly IMR data, used to generate the U charts, are typically publically available, dates of infant deaths, used to create the T and G charts, require a data use agreement with VROs. As was done with these examples, all necessary permissions should be obtained and all legal restrictions should be followed to ensure that privacy and confidentiality concerns are addressed. Finally, as with any analysis involving provisional data, an understanding of the accuracy of these data is vital for interpretation.

For outcomes such as IMR, where continuous learning is particularly useful, the use of SPC charts has great potential for helping MCH practitioners interpret data as future changes are tested and taken to scale. However, realizing the full potential of SPC will require state and local leadership to take several important steps. Relationships and data use agreements with VROs will be needed to obtain the data needed to generate the charts in a timely and ongoing basis. The capacity to produce SPC charts should be incorporated into existing data systems to provide analysis of data in near real-time. Effective use of these methods will require tracking programmatic efforts as well as a plan to address the special causes. Collaboration between those with programmatic and data expertise is needed so that charts and special cause signals can be appropriately interpreted and acted upon to improve the system. Workforce development to increase the capacity of MCH professionals to develop expertise in the theory and use of SPC charts will also be needed to benefit both practitioners as well as the families and children they serve.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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