Published in final edited form as:

Jt Comm J Qual Patient Saf. 2019 April ; 45(4): 295–303. doi:10.1016/j.jcjq.2018.11.003.

Implementing Strategies to Identify and Mitigate Adverse Safety Events: A Case Study with Unplanned Extubations

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Abstract

Background: Patient safety events result from failures in complex health care delivery processes. To ensure safety, teams must implement ways to identify events that occur in a non-random fashion and respond in a timely manner. To illustrate this, we describe our experience with an outbreak of unplanned extubations (UEs) in our Neonatal ICU (NICU).

Methods: Our quality improvement team measured UEs using three complementary data streams. We tested interventions to decrease the rate of UE with success. Three statistical process control (SPC) charts (*u*-chart, *g*-chart, and an exponentially weighted moving average [EWMA] chart) were used for real-time monitoring.

Results: From July 2015 to May 2016, the UE rate was stable at 1.1 UE/100 ventilator days. In early June 2016, we observed a cluster of UEs, including 4 events within one week. Two of three SPC charts showed special cause variation, although at different time points. The EWMA chart alerted the team more than two weeks earlier than the *u*-chart. Within days of discovering the outbreak, our team identified that the hospital had replaced the tape used to secure endotracheal

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Financial Disclosure:

There are no relevant financial disclosures.

Conflict of Interest:

The authors disclose no relevant conflicts of interests.

tubes with a nearly identical product. After testing multiple tape products over the next month, we selected one that returned our system to a state of stability.

Conclusions: Ongoing monitoring using SPC charts allowed early detection and rapid mitigation of an outbreak of UE in our NICU. This highlights the importance of continuous monitoring using tools such as SPC charts that can alert teams to both improvement and worsening of processes.

Introduction:

Unplanned extubations (UEs) are an important patient safety metric in the Neonatal ICU (NICU).^{1,2} Unplanned extubations are associated with patient harm¹ and have become the focus of large, national initiatives to improve the safety of neonatal care.^{2,3} Similar to other patient safety events, UE is the ultimate outcome of a failure at some point in a complex health care delivery process. This failure may occur at the provider, task, tool/technology, physical environment, or organizational level.⁴ Given the inherent complexities of these processes, a robust system to measure and identify both planned improvements and unexpected worsening and rapidly mitigate events is critical to providing safe health care.⁵

Statistical process control (SPC) charts are commonly used graphical tools to monitor quality improvement (QI) or patient safety measures. While SPC methods have their origin in manufacturing and industrial engineering,⁶ they are commonly used in health care applications.⁷ Many types of SPC charts exist, each with its own statistical basis, assumptions, strengths, and weaknesses. The choice of the most appropriate chart depends on multiple factors, including the type of measure, the frequency of data collection, and the goals of the measurement or monitoring process.⁶ Proper chart selection is key to detecting both improvement and worsening of QI and patient safety metrics.

The objectives of this report are to (1) highlight the importance of ongoing monitoring of patient safety metrics, even after improvements have been made, and (2) illustrate the importance of an analytic strategy, using SPC methods, that provides timely data about both process improvement and worsening. To accomplish this, we describe our experience with detecting and mitigating an outbreak of UEs in our NICU.

Methods:

Setting and Ethics:

Our 98-bed, Level IV (regional),⁸ academic NICU, part of a 267-bed children's hospital, includes two geographically distinct units in adjacent hospitals: a 20-bed unit housing mostly inborn preterm infants and a 78-bed unit for infants with medical and surgical conditions, including those who are outborn. The children's hospital (including the NICU) is part of a larger, 1,019-bed, comprehensive medical center composed of multiple hospitals. The NICU receives nearly 1500 admissions annually and is supported by a full range of medical and surgical subspecialty services. Approximately 400 infants are mechanically ventilated in the NICU annually, for a total of 4000 ventilator days. The Institutional Review Board at our medical center granted our team a QI exemption for this initiative.

Measures:

Our primary outcome measure was the rate of UEs per 100 ventilator days. A UE (numerator for our outcome) was defined as any removal of an endotracheal tube (ETT) that was not planned in advance by the medical team. This included ETTs dislodged by the patient and those removed inadvertently during routine nursing or medical care. Endotracheal tubes that were intentionally removed during a code or a period of patient decompensation were included as a UE unless there was objective evidence that the ETT was in the trachea and patent.¹ Objective evidence included breath sounds on auscultation, presence of expiratory ventilator waveforms, or positive color change on an end-tidal CO₂ detector. Unplanned extubations were identified through three data streams: (1) the hospital voluntary incident reporting system, (2) mini-root cause analysis forms completed by the bedside team immediately after a UE, and (3) a record kept by the neonatal respiratory therapists of all UEs in our NICU. Ventilator days (denominator for our outcome) included all days when an infant was ventilated through an ETT (excluded tracheostomies).

Interventions:

The NICU Mechanical Ventilation Safety (MVS) team was formed in January 2014 with the goal of decreasing the rate of UE in the NICU. At the time, the specific UE rate was unknown although NICU leadership thought it was higher than desirable. The MVS team includes respiratory therapists, bedside nurses, neonatal nurse practitioners, physicians, a data analyst, and a systems engineer with expertise in patient safety. This team met monthly to review UEs during the prior month, discuss ongoing data, and plan future improvement initiatives. Based on prior literature,⁹ our team's specific aim was to reduce the UE rate to <1/100 ventilator days. From July 2015 through May 2016, our team tested interventions to achieve our goal. These included use of: (1) a standardized checklist prior to retaping the ETT for all infants, (2) a medical grade liquid adhesive during ETT taping in infants >32 weeks postmenstrual age (PMA), and (3) two respiratory therapists and one bedside nurse to retape ETTs in infants <28 weeks PMA (later expanded to all infants <32 weeks PMA). These interventions resulted in substantial improvements in the UE rate (Figure 1). This report describes the outbreak of UE that occurred subsequent to these improvements, detection of that outbreak, and our team's response.

Data Analysis:

Our team used three SPC charts, implemented at different times during our work, to monitor UEs. Beginning in February 2014 with the onset of UE data collection, we plotted the rate of UE on a *u*-chart.¹⁰ We used monthly subgroup sizes to coincide with our monthly team meetings and to align with reporting of monthly UE rates to hospital leadership. As QI methodologic knowledge grew in our team, we added two other SPC charts beginning in July 2015: a *g*-chart analyzing the number of ventilator days between UEs¹¹ and an exponentially weighted moving average (EWMA) chart of weekly UE rates.^{12,13} *G*-charts allow the user to plot events (UEs in our case) as they occur rather than waiting for the end of a pre-specified sample period, as with the *u*-chart. Our EWMA chart^{12,13} contained weekly subgroup sizes, weighting constant (λ) of 0.2, and a baseline/target value of 1.0

UE/100 ventilator days.¹³ We chose the three charts for complementary but different purposes. Comparison of the three charts can be found in Table 1.

The u -chart was our primary chart and contained monthly subgroup sizes. Because the width of the control limits on a u -chart depend on the mean rate and each subgroup sample size,¹⁰ the monthly subgroup sizes were too small to allow us to have a lower control limit (LCL), limiting our ability to detect improvement rapidly. To overcome this limitation, we followed a g -chart. G -charts, based on a geometric probability distribution, are more sensitive to improvement for rare events and we hypothesized that this would allow us to note improvements more rapidly during testing of interventions compared to using a u -chart alone.¹⁴ To detect small, persistent shifts in the rate of UE that might not be readily apparent on the u - or g -charts, we used an EWMA chart. These charts allow the user to graph weighted moving averages of data of interest (rates, times, etc.) and assign more importance to the most recent points compared to historical data. Because the EWMA control limits do not depend on sample size, we used weekly data for this chart. For the u - and g -charts, we used the Western Electric Rules¹⁵ (Sidebar 1) to identify special cause variation.^{10,16} Since the EWMA chart contained correlated (non-independent) data, we identified special cause variation with one point outside of the control limits.¹³ We shifted our mean and control limits only after noting special cause variation with an assignable cause. Data were housed in the Research Electronic Data Capture program¹⁷ at our medical center. All SPC charts were constructed using QI Macros for Excel (KnowWare International Inc, Denver, CO).

Results:

From February 2014 to June 2015, the rate of UE in our NICU was stable at 2.23 UE/100 ventilator days (Figure 1). Beginning in July 2015, special cause variation was identified with a “shift” of eight consecutive months below the mean. This special cause variation corresponded to testing the three interventions designed to improve ETT securement and standardize the retaping process. From July 2015 to May 2016, our UE rate remained stable at 1.1 UE/100 ventilators days as we continued to refine these interventions to improve ETT securement.

In early June 2016, we observed a cluster of UEs, including four events within one week. Two of the three SPC charts met special cause criteria (Figures 1 to 3), although at different time points. As the cluster of UEs occurred early in the month, we waited until the end of the month to determine on our u -chart if these events represented random variation or true process decrement. When we charted the data on July 1, 2016, we identified special cause variation with one point above the upper control limit (UCL) (Figure 1). Special cause variation criteria were nearly met on the g -chart with seven points below the center line (Figure 2). The EWMA chart showed evidence of special cause variation on June 12, 2016 with one point above the UCL (Figure 3), providing the earliest evidence that the cluster of UEs was unlikely to be due to random variation. As a result of the SPC chart signal, the lead respiratory therapist on our team investigated the outbreak and discovered that the tape used to secure ETTs in our unit (1/2-inch cloth tape) had been replaced with a product that was nearly identical in size and appearance. Our team (and almost all NICU staff) was unaware that the ETT tape used in our NICU prior to May 2016 (“old” tape) had been discontinued

by the manufacturer and hospital central supply had replaced the product with a similar but different product (“new” tape). The point above the UCL in the EWMA chart (Figure 3) corresponded to the timing of the new ETT tape being stocked in large quantity in our NICU.

With evidence of a decrement in performance, we attempted to mitigate the effect of the change in tape by procuring all of the old ½-inch cloth tape still available in the hospital and allocating it to be used for NICU ETT taping only. Concurrent with this in mid-June 2016, we began testing alternative ETT tapes. To do this, team members reached out to colleagues at other centers to inquire about ETT tapes used in their NICUs. From this, we identified five potential tapes for testing. We then conducted a one-week taping trial on nasogastric (NG) feeding tubes. We divided our NICU into five geographic sections and used only one type of tape for NG tube securement in each section. We chose to test on NG tubes first to ensure that only products that met the unique needs of preterm infants (strength, durability when damp, able to be removed without damaging immature skin) were applied to ETT testing since dislodgement of an ETT had potentially higher consequences than dislodgement of an NG tube. Two tape products were eliminated during NG tube testing. The team tested the three remaining products on ETTs over a 2.5-week period in mid-July 2016. Each intubated infant during the trial was assigned one of the three tapes for ETT securement. We used a quantitative and qualitative process to evaluate each tape. A folder containing paper forms (redacted example of a completed form is shown in Figure 4) was placed at the bedside of each infant in the trial, and a form was completed by the bedside nurse and the respiratory therapist at the end of each shift. We continued to follow UEs during this trial. After 2.5 weeks, none of the three tapes showed differences in UEs though one tape was superior to the other three in qualitative feedback from the bedside staff. This tape was implemented in our NICU for all ETT taping by the end of July 2016.

By the end of July 2016, our system had returned to statistical control (Figure 1). However, because the old ETT tape was replaced with a different product, our system fundamentally changed. The UE rate nearly returned to the original baseline rate at 2.1 UE/100 ventilator days and remained stable for the following year.

Discussion:

This report describes our experience with identifying and mitigating a sudden and unexpected increase of UEs in our large NICU. The increase was temporally associated with discontinuation of a specific type of tape used to secure ETTs to the face of ventilated infants. Continuous monitoring of UEs in our NICU and real-time use of SPC charts sensitive to system change enabled us to detect the increase, identify the probable cause, and develop solutions to bring our system back into a state of statistical control within weeks of discovery. This report highlights the importance of (1) a systems approach to neonatal patient safety, (2) continuous monitoring of key patient safety metrics, and (3) a robust analytic strategy to identify both improvement and decrement in QI and patient safety work. Further, it demonstrates how the application of fundamental QI elements can be used to promote and ingrain collective mindfulness (or safety culture), the characteristic work processes of high-reliability organizations.^{18,19}

As in our NICU, most neonatal and pediatric hospitalizations in the United States occur within larger medical systems.²⁰ This presents challenges to choosing safe and appropriate medical products, such as tape or ETT securement devices, that meet the needs of the diverse patient populations hospitalized in a large medical center. After we discovered the abrupt increase of UEs and identified the probable cause, our team tested several tape products in our NICU and ultimately chose a product that was not used to secure ETTs in other settings in our medical center. Although this product met the unique requirements for ETT securement in neonates, its properties limited its effectiveness in older intubated patients. We have chosen not to include the manufacturers and models of the tapes that were tested in our unit for multiple reasons. Chief among these reasons is that although the new tape did not meet the specific needs of our NICU, this may be a reflection of our system and not necessarily a reflection of the inherent qualities of the tape(s). Like most products used in neonatal intensive care, none of the tape manufacturers advertise any of the tapes we tested to be used to secure neonatal ETTs, although tape is the most commonly used method for securement of ETTs in the NICU. Indeed, all tape products are off-label (for lack of a better term) for neonatal ETT securement. One of our goals in writing this report was to help other centers/teams recognize that individual components of their own system should be evaluated for their optimal use within that system. This report highlights the fact that a one-size-fits-all approach to choosing medical supplies/devices across a hospital system can have serious adverse effects on patient safety. To ensure safe care for all patients, systems must be designed to meet unique requirements of high-risk subpopulations. Methods such as failure modes and effects analysis (FMEA),^{21,22} structured what-if technique (SWIFT),²³ combinations of FMEA and SWIFT,²⁴ and human factors engineering methods²⁵ such as usability testing²⁶ must be increasingly used to prospectively identify safety hazards. Based on the experience we report, we have begun to incorporate these techniques as we design interventions to decrease the rate of UE.

Even with improved system design, ongoing vigilance regarding patient safety metrics is still needed. Our report highlights the importance of using an analytic strategy capable of timely detection of both planned process improvement and unexpected worsening. Statistical process control charts provide the ability to discern random variation, inherent in all systems, from variation with an assignable or special cause.²⁷ Like all statistical tests, each SPC chart has assumptions, strengths, and weaknesses.^{28,29} Knowledge of these properties is paramount in choosing a chart or combination of charts to meet individual project needs. Because the EWMA control limits do not depend on sample size, we used weekly data for this chart. As a result, the EWMA chart detected the increased occurrence of UEs 19 days earlier than the *u*-chart. We used this time to mitigate the increase in UEs and potentially prevent further patient harm. It is possible that, had we used more liberal rules for identifying special cause, we may have detected the outbreak earlier.

Although we report some success, our work has limitations. First, primary prevention of the increased UEs would be the safest care. Although we could not have prevented discontinuation of the ETT tape by the manufacturer, a more robust process to anticipate the effect of the change on all aspects of the medical system might have mitigated the result. We report our experience so that others might learn from our successes and our failures, as we have attempted to do. Second, although we intentionally selected a specific combination of

SPC charts, other combinations could have been used and may have produced similar or even more timely data.³⁰ Third, given our pragmatic QI approach, we cannot say with absolute certainty that the change in ETT tape was directly responsible for the decrement in the UE rate. While there was a strong temporal relationship, it is possible that other factors of which we were not aware contributed as well. Fourth, our data streams for identifying UE depended on voluntary reporting of bedside staff, introducing the possibility that some events were not captured. Finally, although many software platforms are available to generate SPC charts, some basic statistical knowledge is needed to use them. A detailed discussion of how to build and interpret each SPC chart as well as the statistical basis for each is beyond the scope of this article. However, many excellent resources are available that describe SPC methods in general^{6,27,31} and details of the individual SPC charts used by our team.^{11–14,32}

Conclusion:

Our experience with identifying and mitigating an outbreak of UE in our large, academic NICU highlights the importance of continuous monitoring of patient safety metrics with tools such as SPC charts that are sensitive to both improvement and worsening. We encourage health care providers to put an end to QI or patient safety “projects” and embrace the permanent task of building, monitoring, and refining sustainable safe systems.

Acknowledgments:

The authors acknowledge and thank the astute nurses and respiratory therapists in our NICU whose knowledge provided the critical insight to explain the signals in our data.

Funding Source:

Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1 TR000445 (Research Electronic Data Capture program). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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Sidebar 1:**Commonly Used Rules to Identify Special Cause Variation on Statistical Process Control Charts¹⁰**Western Electric Rules¹⁵

1. One of more points outside of the control limits
2. Two of three consecutive points outside the two-sigma warning limits but still inside the control limits
3. Four of five consecutive points beyond the one-sigma limits
4. Eight consecutive points on one side of the center line

Additional commonly used rules

1. Six consecutive points in a row increasing or decreasing
2. Fifteen points in a row within the one-sigma limits on either side of the center line
3. Fourteen consecutive points alternating up and down on either side of the center line
4. Eight consecutive points on either side of the center line outside the one-sigma limits
5. An unusual or nonrandom pattern in the data
6. One or more points near a warning or control limit

Rule applicability depends upon chart type and project goals.

Figure 1:

Statistical Process Control Chart (u-chart) of Monthly Unplanned Extubation Rate in the NICU Evidence for special cause variation is seen in (1) July 2015—shift after beginning testing of endotracheal tube (ETT) taping interventions, (2) June 2016—one point above the upper control limit (UCL) after ETT tape was changed, and (3) July 2016—shift after switching to a new ETT tape. Gray The gray area represents the time period covered by the g- and exponentially weighted moving average (EWMA) charts.

Figure 2:

Statistical Process Control Chart (g-chart) of Ventilator Days Between Unplanned Extubations Evidence for special cause variation was seen on (1) July 15, 2015—one point above the upper control limit (UCL) after beginning testing of endotracheal tube (ETT) taping interventions and (2) June 2, 2016—one point above the UCL after expanding our ETT retaping guidelines. A shift of 7 points below the center line (CL) occurred after the ETT tape was changed, which did not meet special cause criteria.

Figure 3:
Statistical Process Control Chart (Exponentially Weighted Moving Average [EWMA] Chart) of Unplanned Extubations Special cause variation criteria were noted on June 4, 2016 with one point above the upper control limit (UCL). CL, center line; LCL, lower control limit.

Tape Trial

Once this form is complete, please return it to the folder at the patient's bedside. If you have any questions, please contact [REDACTED]

Type of tape: [REDACTED] Patient's Gestational Age: 37

Staff Member Evaluating Tape: [REDACTED]

Date Evaluation Was Completed: [REDACTED] Shift: ☒ AM ☐ PM

Did you replace the tape on your shift? ☒ Yes ☐ No

If you replaced the tape on your shift, please answer questions 1 – 6. If not, answer questions 1 – 3.

1. Did the tape adhere to the tube sufficiently?
☒ Yes ☐ No (please provide explanation)
2. Did the tape adhere to the skin sufficiently?
☒ Yes ☐ No (please provide explanation)
3. How does this tape compare to the tape we previously used ([REDACTED])?
☒ Better ☐ Same ☐ Worse
Comments: _____
4. Was the adhesive from the tape difficult to remove from either the patient's skin or the tube?
☐ Yes (please provide explanation) ☒ No
5. Did the existing tape cause any skin breakdown?
☒ Yes (please provide explanation) ☐ No
Skin was very dark red p removal of old tape (very carefully removed)
6. Did you use any additional adhesive product when placing tape on patient?
☒ Yes, Skin prep ([REDACTED]) ☐ Yes, [REDACTED] ☐ No
due to above ↑ [REDACTED] was not used with new tape job

Figure 4:
Example of Completed (Redacted) Qualitative Form Used to Assess Tapes During Endotracheal Tube Taping Trial

Table 1:Comparisons of the Three Statistical Process Control Charts Used^{10–15,32}

	<i>u</i> -chart	<i>g</i> -chart	EWMA chart
Each point (subgroup) on the chart represents...	The event rate (UEs) for each individual time period	One event (UE)	<ul style="list-style-type: none"> - EWMA statistic (the weekly rate of UE multiplied by a weight) - Weight value depends on the weighting constant (λ) and the timing of the observation - Recent observations receive higher weights
x-axis	Time	Time	Time
y-axis	UE rate per 100 ventilator days	Number of ventilator days (area of opportunity) between UEs	Exponentially weighted moving average of UE rate per 100 ventilator days
Center line	Average of all subgroups ($\bar{u}$)	Theoretical median = Average of all subgroups ($\bar{g}$) * 0.693	Average of all subgroups (μ_0)
Width of control limits depends on.	<ul style="list-style-type: none"> - Sigma levels chosen (standard convention = 3) - $\bar{u}$ - Number of observations in each subgroup 	<ul style="list-style-type: none"> - Sigma levels chosen (standard convention = 3) - $\bar{g}$ - No lower control limit 	<ul style="list-style-type: none"> - Sigma levels chosen (standard convention = 3) - μ_0 - Weighting constant (λ) - Sample number/time (i) - σ (usually calculated using the screened moving average)
Determining special cause variation	Standard rules	Standard rules	One point outside the control limits
Special considerations	<ul style="list-style-type: none"> - Easy to understand - Allow for varying subgroup sizes 	<ul style="list-style-type: none"> - There is no lower control limit - To use the shift rule (8 points above or below the center line), the theoretical median should be used as the center line - Allow each event to be evaluated without waiting for the end of a time period - Useful for monitoring rare events or processes with low rates 	<ul style="list-style-type: none"> - Data are correlated (nonindependent) and normal "rules" for special cause variation should not be used - Must choose a weighting constant (λ) and baseline/target value - λ between 0.1 and 0.3 is often used - Useful for detecting small shifts in rates that may not be appreciated on other charts

EWMA, exponentially weighted moving average; UE, unplanned extubation.