

Advanced Statistical Process Control: Challenging Cases and How to Approach them

**APA QI Research Conference
April 24, 2026**

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Disclosures

- Michael Posencheg is an honorarium recipient from Institute for Healthcare Improvement
 - We are going to be using software called QI Macros for some of the exercises. **We have no relationship, financial or otherwise, with QI Macros.** We are using it because they offer a free fully-functional 30-day trial version. *There are many other SPC software options out there that are equally quirky and frustrating as QI Macros.*
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A bit of (presumed) context...

- We know statistical process control (SPC) is pretty useful for quality improvement.
 - We're familiar with SPC theory, and can do a pretty good job making and interpreting common control charts.
 - But, as we do this more, we come across situations where “typical” SPC methods may not be adequate.
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Three Topics

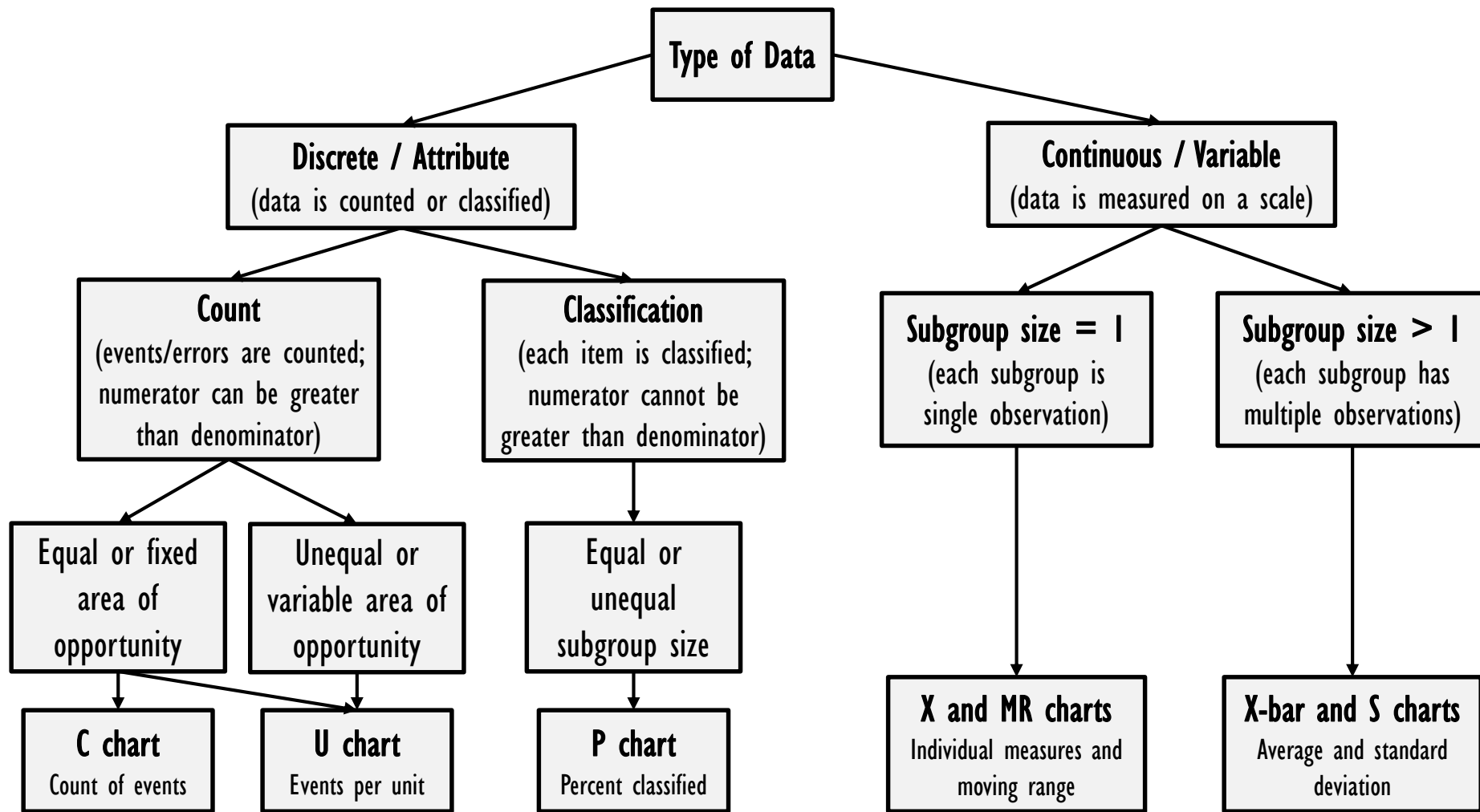
- Fixing and changing the centerline and control limits
 - Non-symmetrically distributed (highly skewed) continuous data
 - Count as continuous data
-

First... A quick review

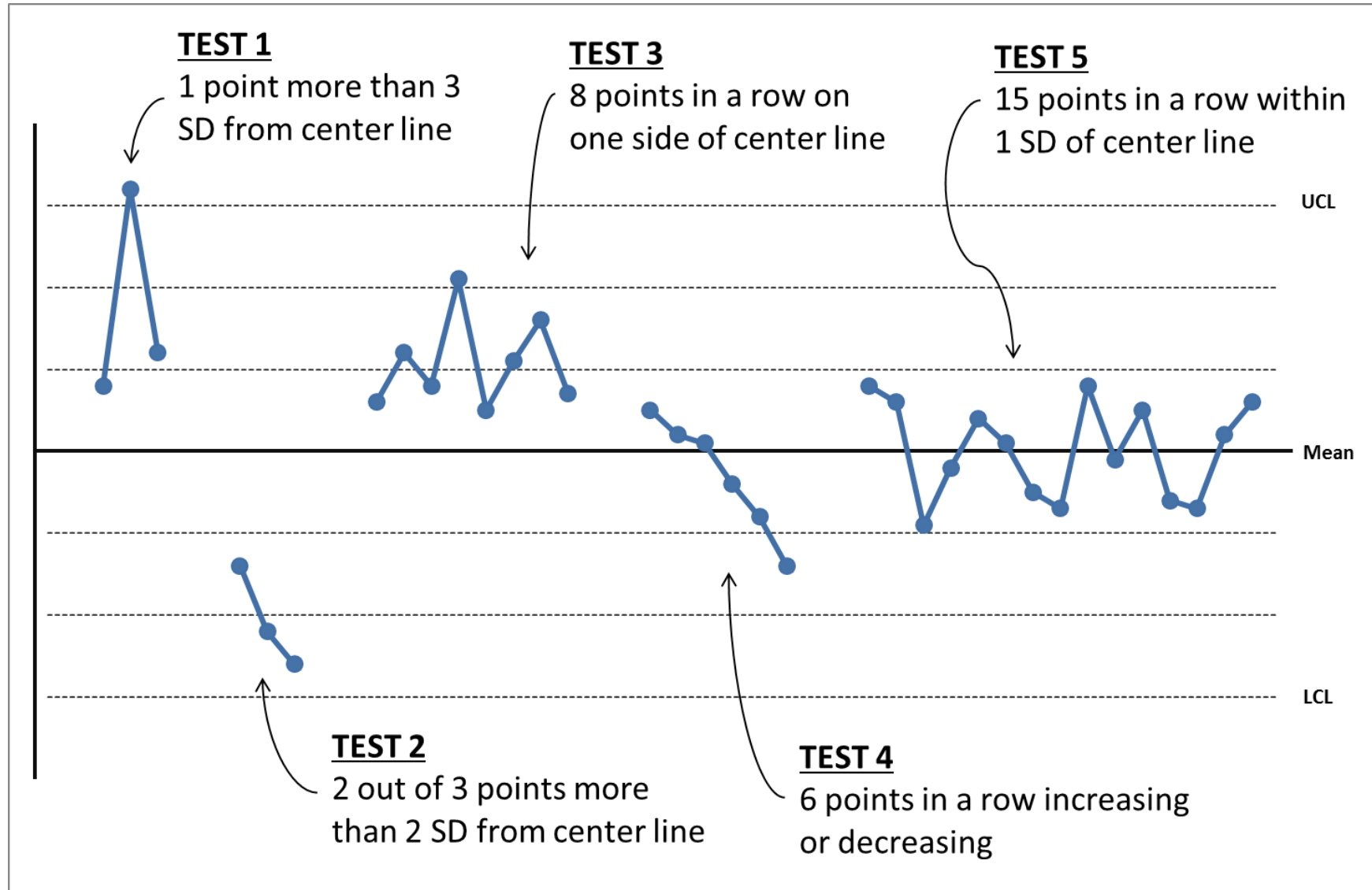
Statistical Process Control

- Tools to help understand variation in data
 - Distinguish signal from noise
(common versus special cause variation)
 - Run charts and control charts
 - Plot data over time
 - Interpret visually and statistically
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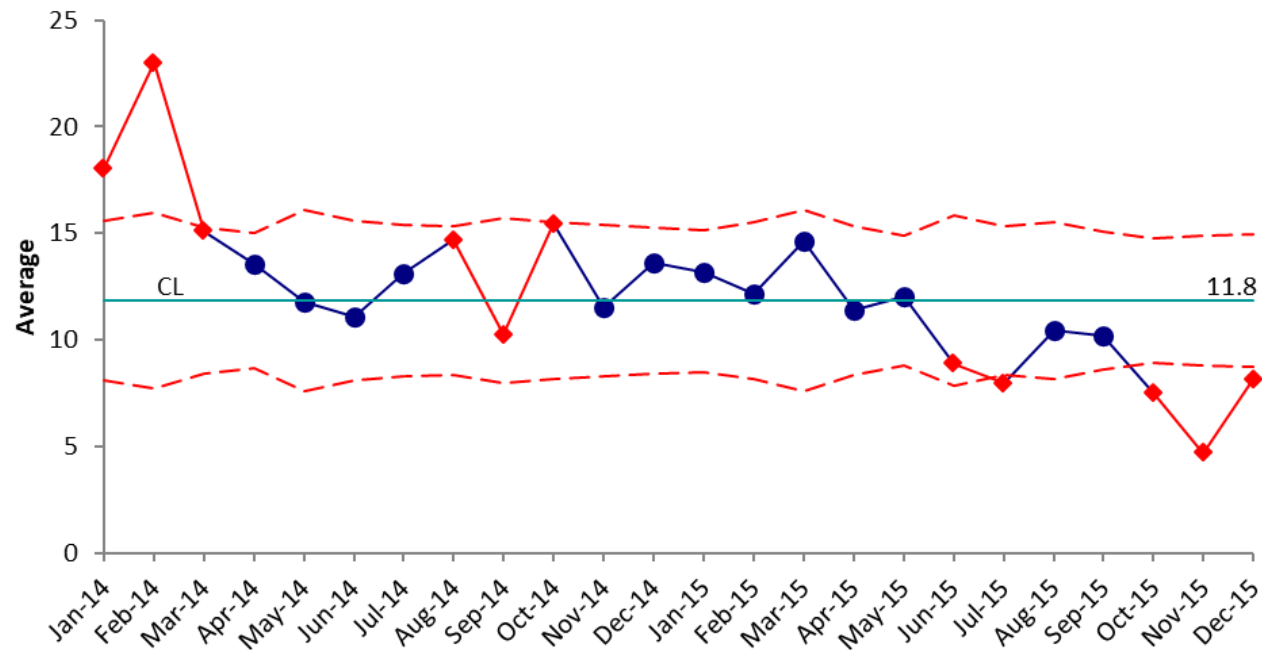
Which Control Chart To Use



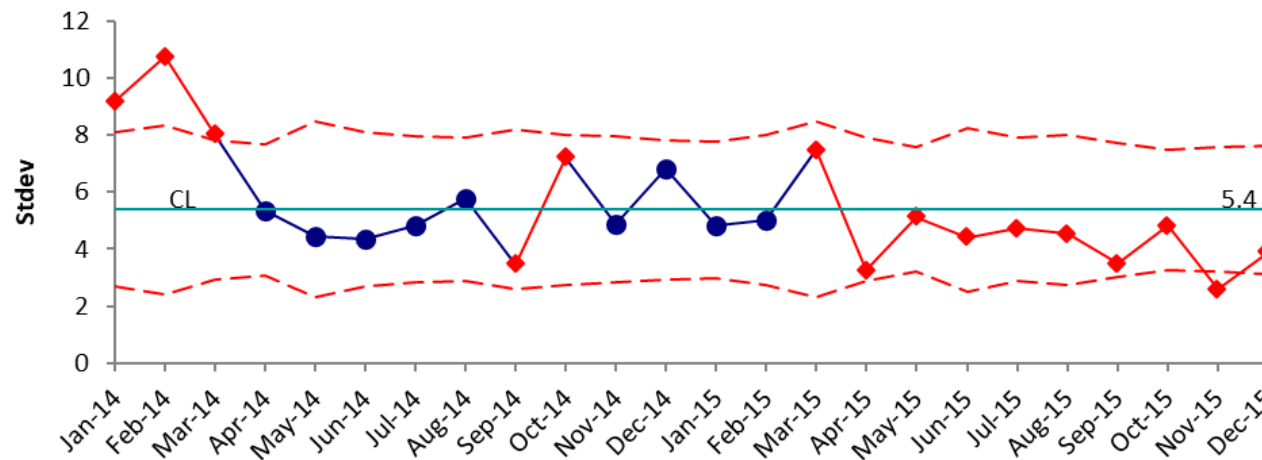
“Rules” for Identifying Special Cause



Time to First Feeding with Mother's Milk - Xbar Chart



Time to First Feeding with Mother's Milk - S Chart



**Once we understand the basics...
we can think about more challenging questions.**

As a reminder...

- In QI, we want to detect change in data.
 - But the change needs to be “real” change.
 - And we want to detect it fast.
 - Using control charts is a good start...
 - But we also need to use them WELL.
-

Three Topics

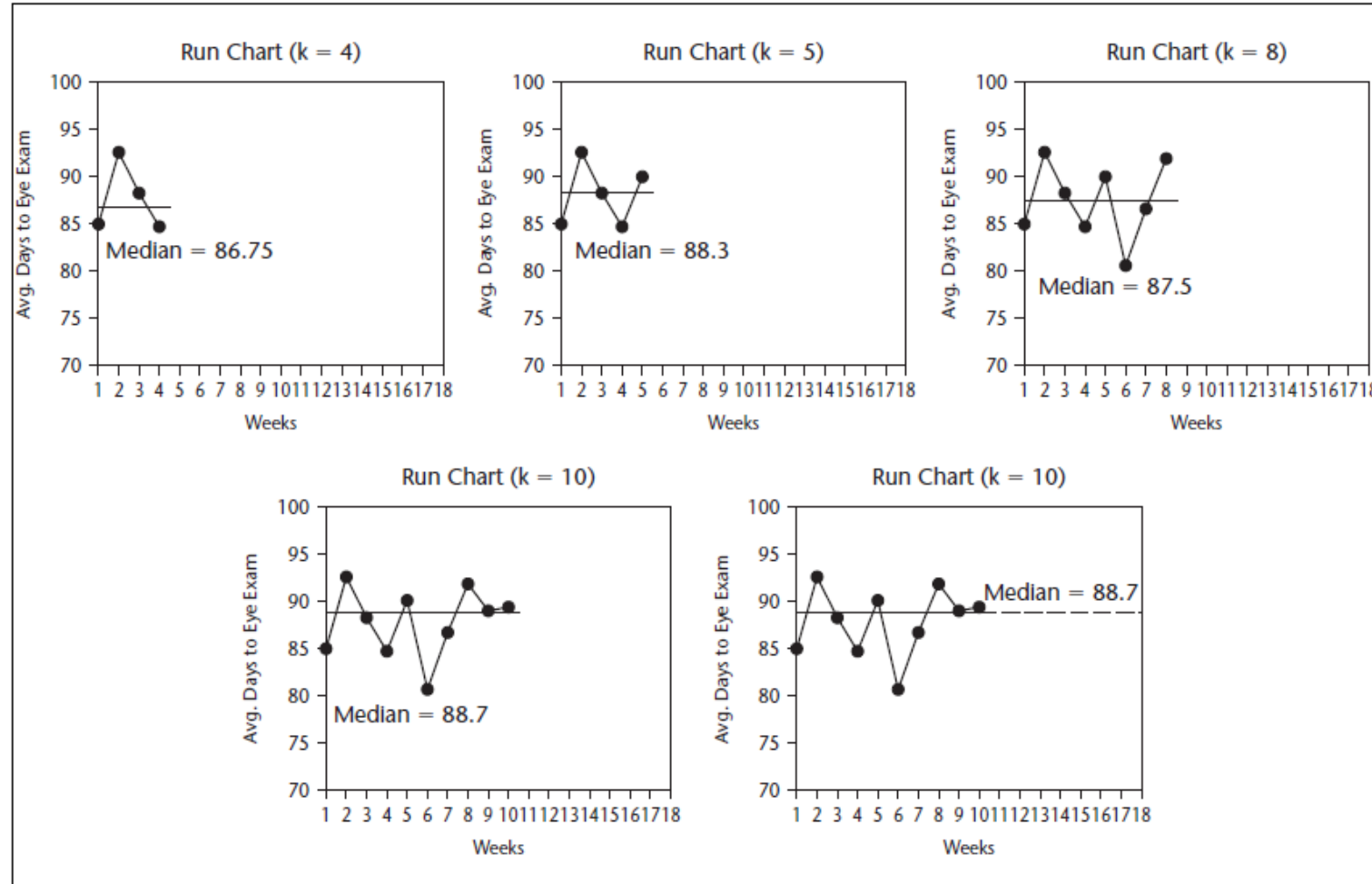
- Fixing and changing center lines and control limits
 - Non-symmetrically distributed (highly skewed) continuous data
 - Count as continuous data
-

Three Topics

- Fixing and changing center lines and control limits
 - Non-symmetrically distributed (highly skewed) continuous data
 - Count as continuous data
-

Establishing a Baseline in a Run Chart

FIGURE 3.23 Run Charts for Waiting Time Data

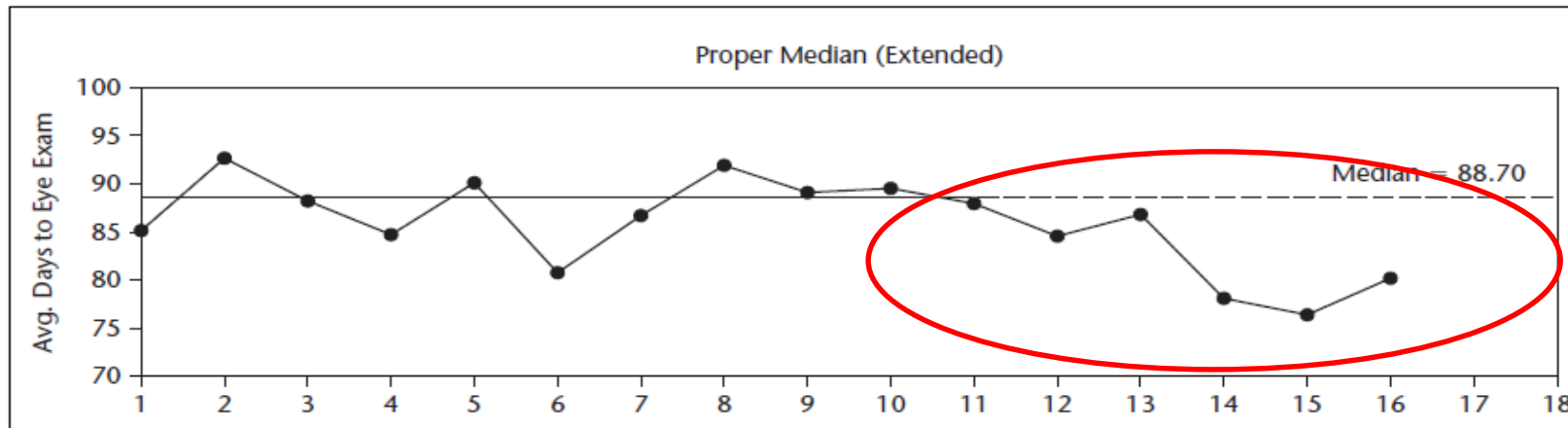


Proper Use of the Median in a Run Chart

- When should we apply a median?
- Will depend on your situation...
 - If very little baseline data, may be only a few data points
 - If want to apply probability-based rules for analysis of run chart need 10 data points for median.
- If graph shows no signals (shift, trend, runs astronomical) and median made from 10 or more data points freeze and extend median into the future
- This will result in earliest possible detection of signals

If median is not fixed and extended, there can be a delayed detection of signals

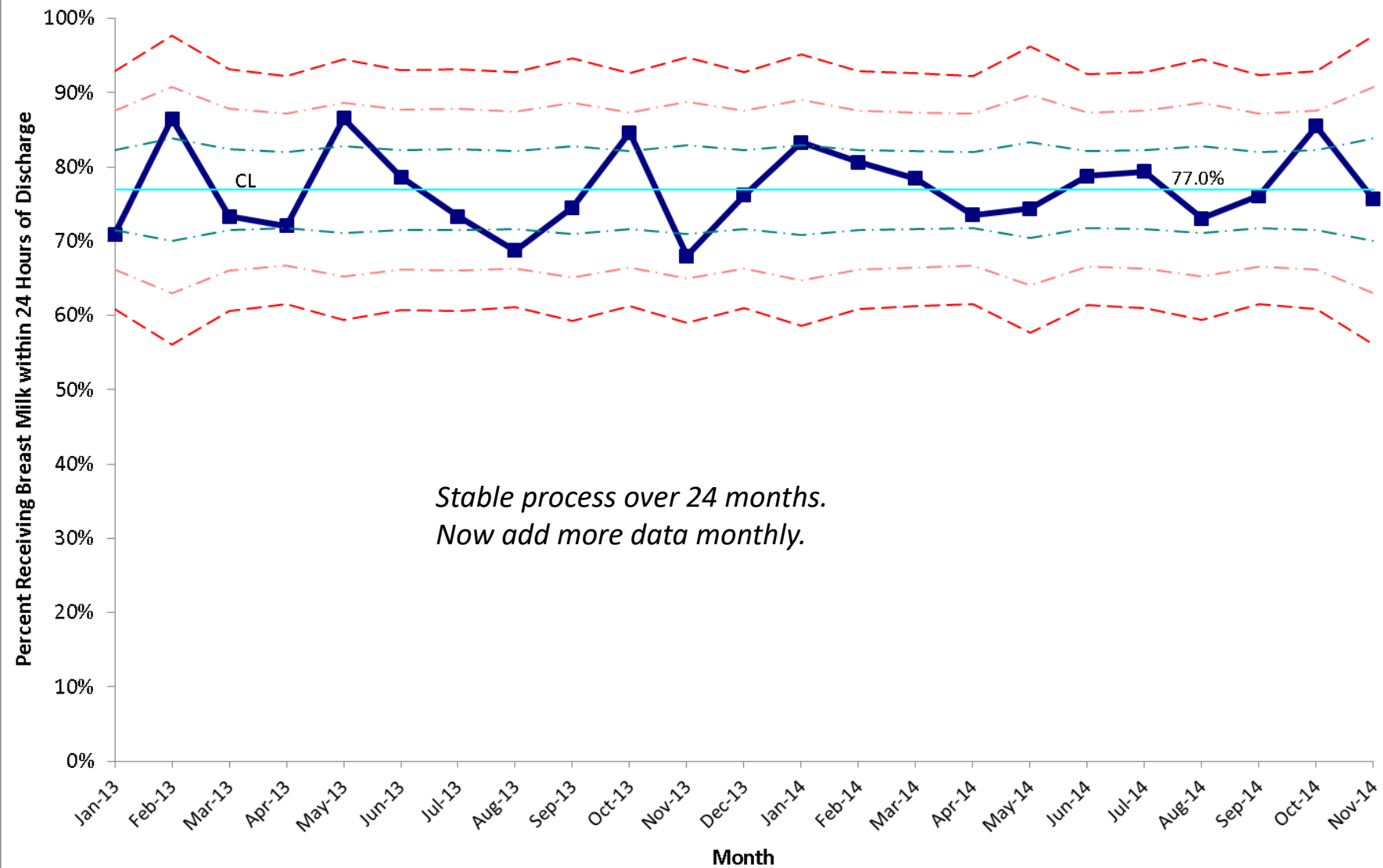
FIGURE 3.24 Delay Detecting Signal with Improper Median Technique



Fixing and Changing Limits

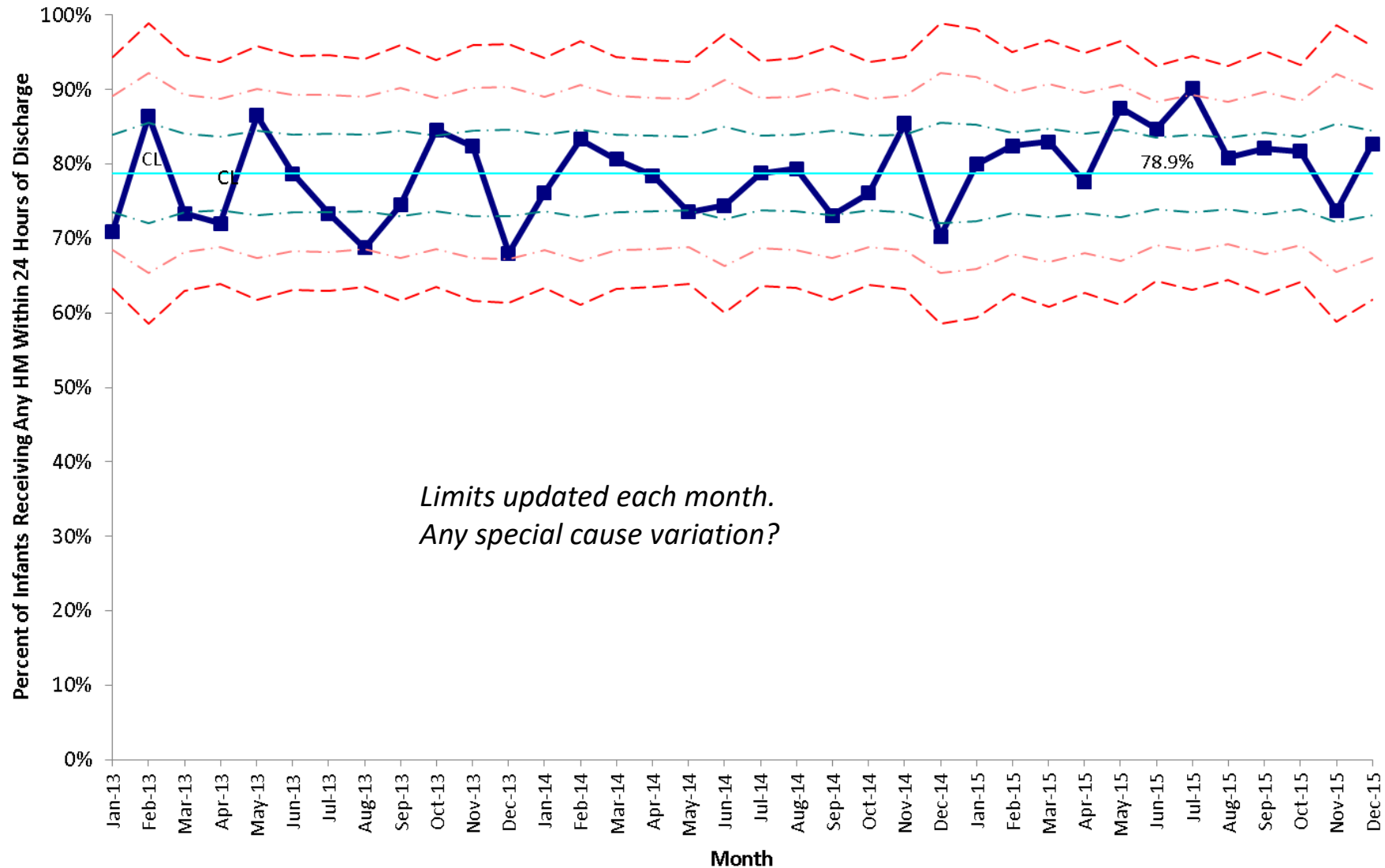
- When making a new control chart, mean and limits are calculated on all measures.
 - When adding additional data to existing chart, need to decide whether to 'fix limits' and compare new points to existing mean, or whether to 'update limits' with new data.
 - When chart shows that a process has changed, need to decide when to use new limits.
-

Any Breast Milk at Discharge P-chart



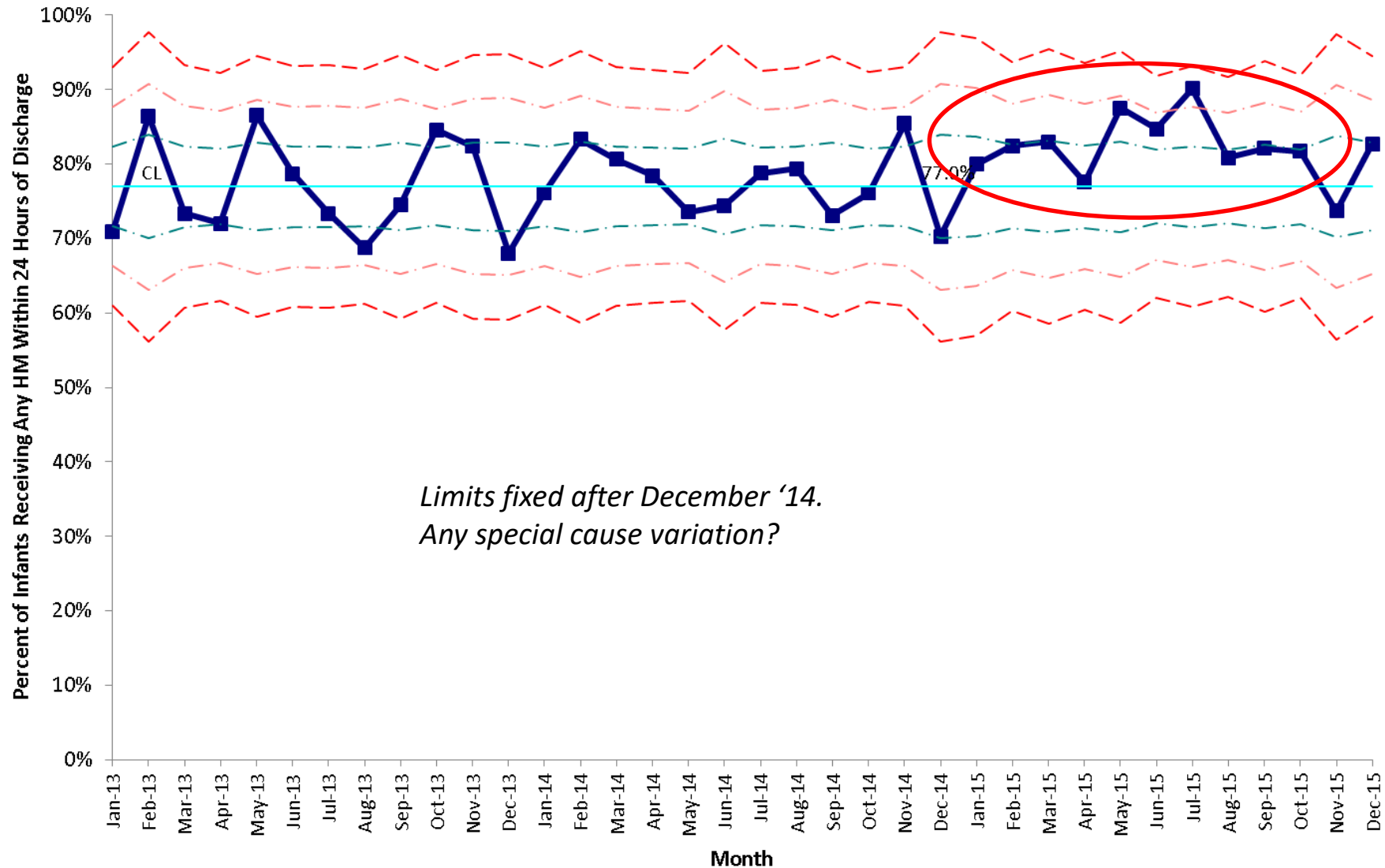
Any Human Milk at Discharge

P-chart: Limits Updated Each Month



Any Human Milk at Discharge

P-chart: Limits Fixed After Dec 12



Fixing Limits

- If a process is stable with approximately 20 data points, and your system knowledge tells you process is stable, limits should be fixed.
 - If a process is unstable and showing (unexpected) special cause, all data points can be used to calculate mean and limits.
 - If a new process is being examined for the first time, all data points should be used to calculate mean and limits.
-

Changing Limits

When should new limits be calculated?

- When data shows a clear change;
- Change can be explained (or persists a long time);
- And the change is expected to last.

Why calculate new limits?

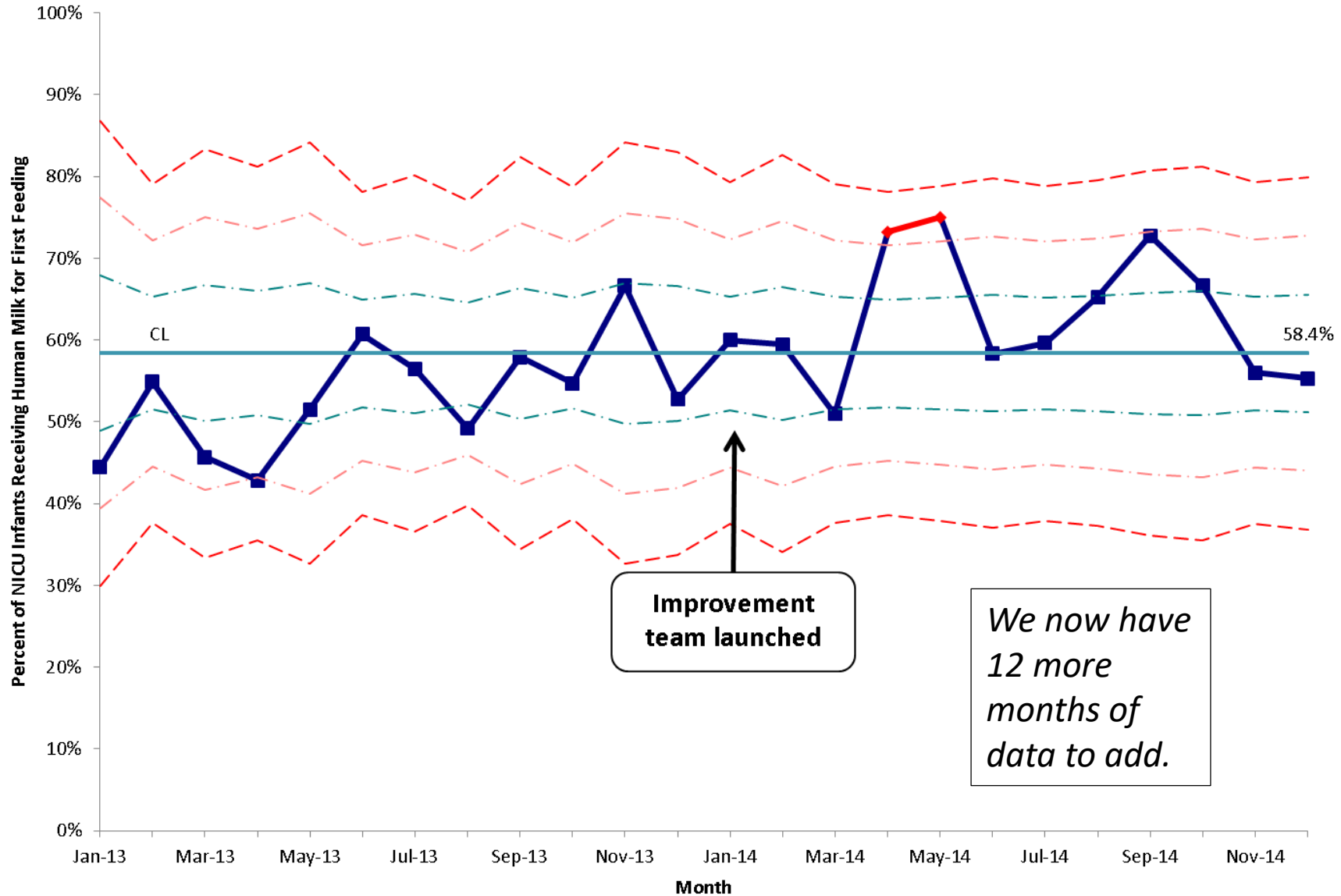
- Compare ongoing process to 'new' baseline;
 - Better describe/illustrate your work.
-

Changing Limits

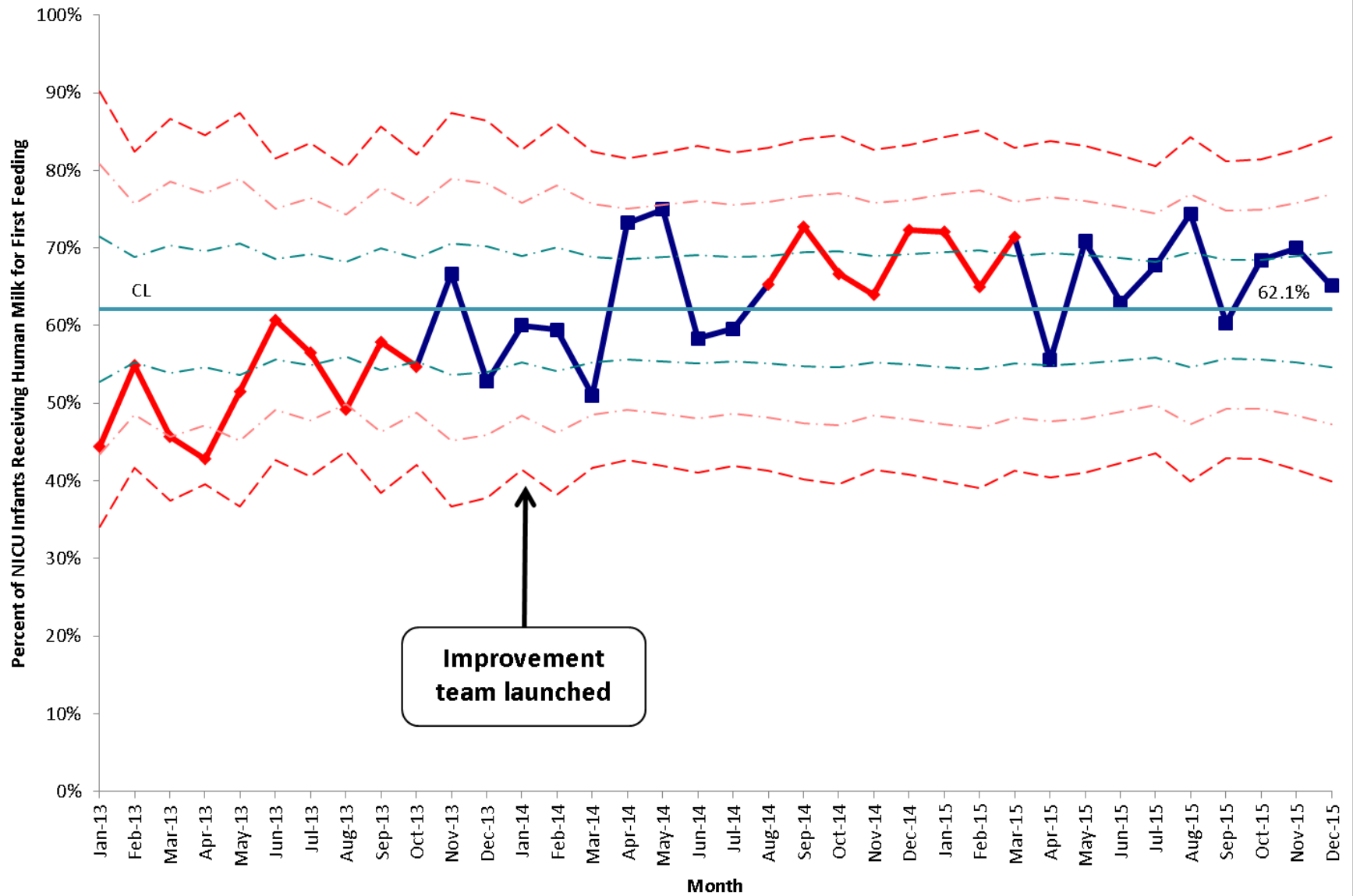
When should limits NOT be changed?

- After a change in practice without evidence of signal or special cause variation
 - After evidence of special cause variation without knowledge of process change (unless it lasts a long time)
 - At a preset interval, i.e., every year
-

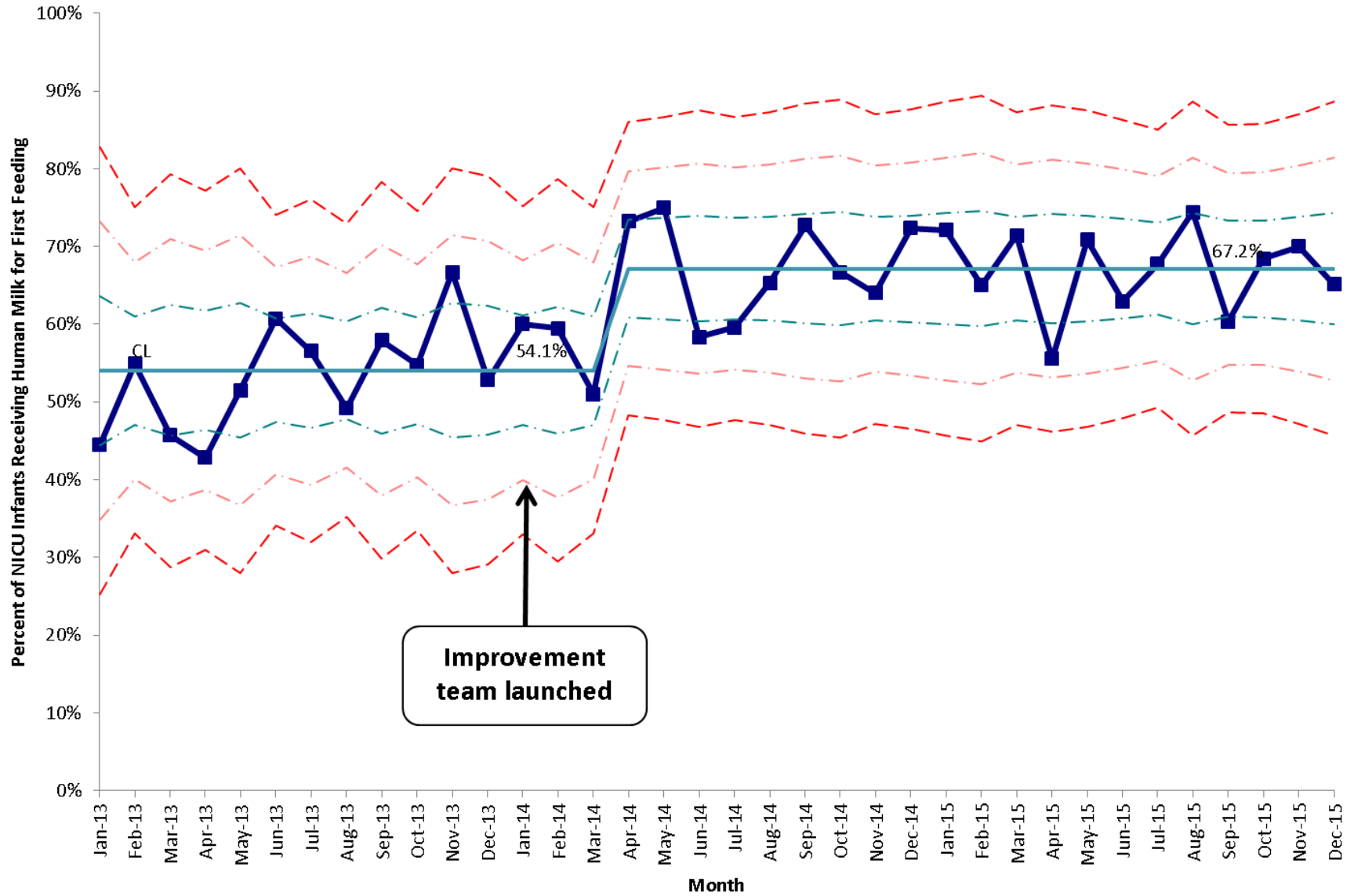
First Feeding as Human Milk, NICU, All Infants, p-chart



First Feeding As Human Milk, NICU, All Infants, p-chart



First Feeding As Human Milk, NICU, All Infants, p-chart



Some Other Thoughts on Limits

- Ideally should have 20 points to establish reliable limits for control charts (10 for run charts)
 - Can have “trial limits” with as few as 12 points, but should then update limits after 20
 - Some knowledge of system and subjectivity almost always needed
-

Fixing and Changing Centerline and Limits

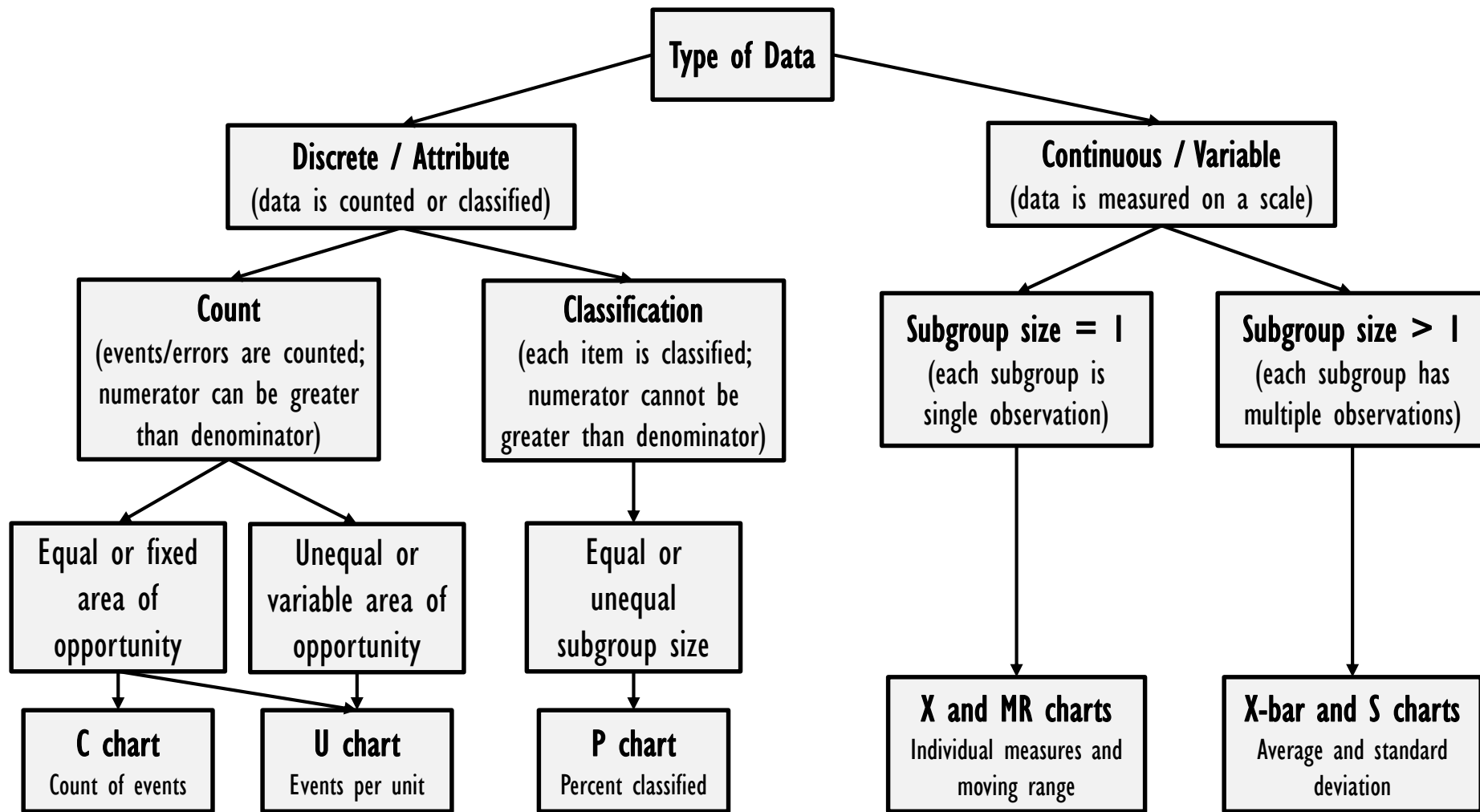
Hands-on Examples!

Three Topics

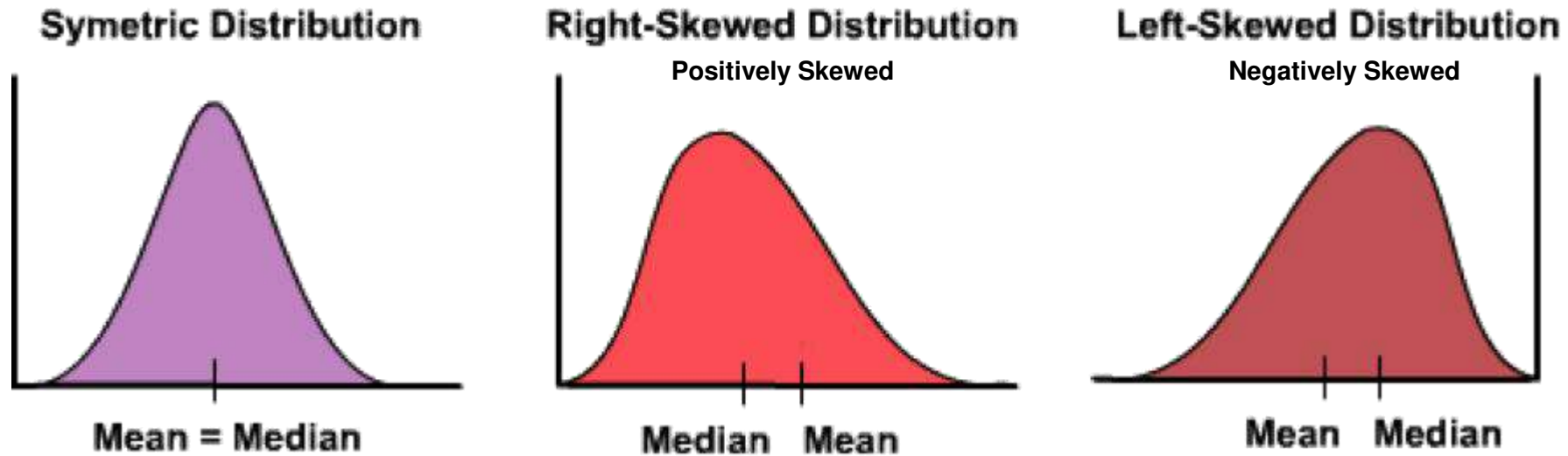
- Fixing and changing the centerline and control limits
 - **Non-symmetrically distributed (highly skewed) continuous data**
 - Count as continuous data
-



Which Control Chart To Use



Skewed Continuous Data

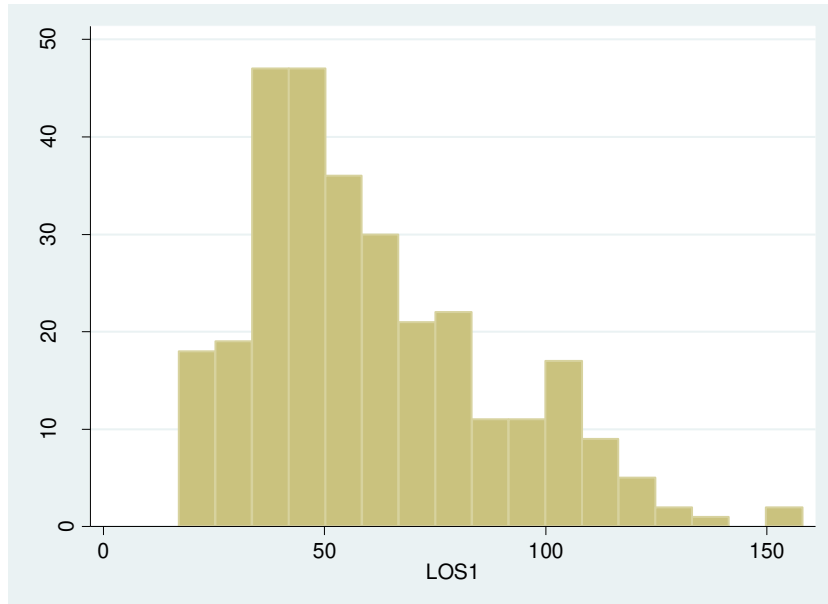


- Skewness= the tendency of the data distribution to be non-symmetrical
- Skewness can be positive (rightward) or negative (leftward)

Skewness may affect the validity of control charts (and other statistical tests) that are based on the normal distribution and impact the application of probability-based rules for detecting special cause variation

What measures have you encountered in your QI work that are highly skewed?

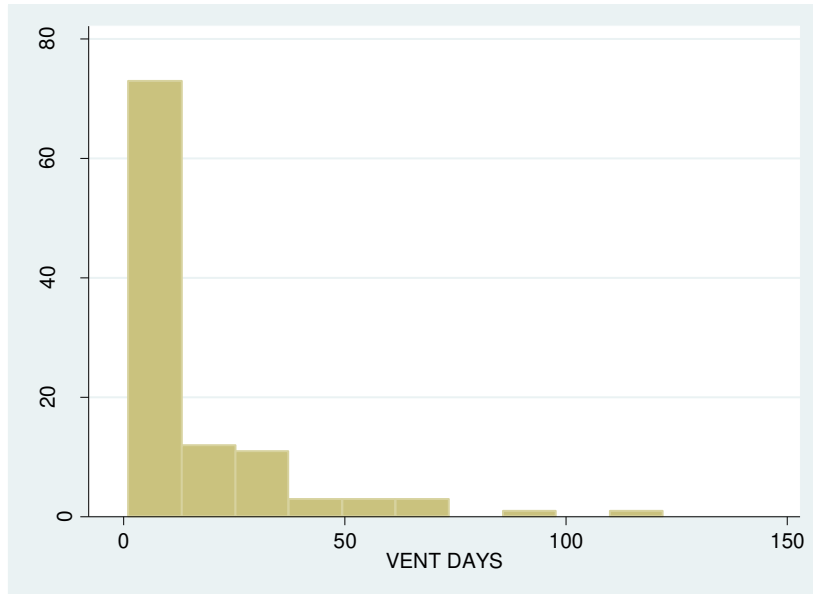
Length of Stay (Infants Discharged Home)



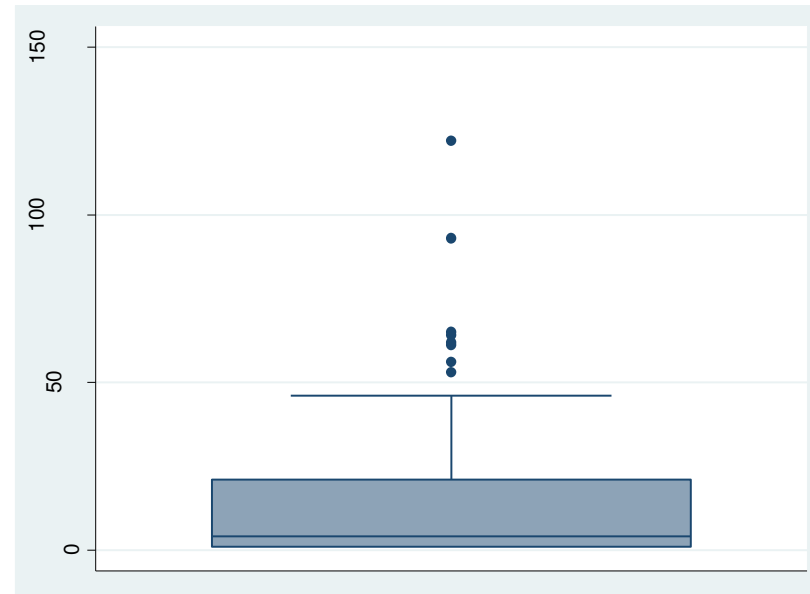
Mean= 60.7
Median= 54

- *Is this distribution symmetric?*
- *Is it right (positively skewed) or left (negatively skewed)*

Ventilator Days (Among Intubated Infants)



Mean= 14
Median= 4



Median= 4
25th percentile= 1
75th percentile= 21

- *Is this distribution symmetric?*
- *Is it right (positively skewed) or left (negatively skewed)*

Normality (Symmetric Distribution) Assumption?

- The X-bar/S and X/mR charts assume that the distribution of the measure is normal (or approximately normal)
- X-bar charts are less sensitive to this assumption because the Central Limit Theorem assures the averages of any distribution will approach a symmetric (normal) distribution as the number of averaged values increases
- I charts are more sensitive to asymmetric distributions and the skewness of the data must be understood before making and/or interpreting control charts
- The use of control charts in skewed distributions causes an increase of Type 1 error (false positive)

XBAR S CHART (FOR CONTINUOUS DATA IN SUBGROUPS)

Symbols Associated with Xbar S Charts

X	Individual measurement of quality or characteristic
n	Subgroup size (number of measurements per subgroup)
k	Number of subgroups used to develop limits
Σ	Summation symbol
sqrt	Square root function
Xbar	Subgroup average
Xbarbar	Weighted average of the averages of all the subgroups
S	Subgroup standard deviation
Sbar	Weighted averages of the standard deviations of all the subgroups
A ₁ , B ₁ , B ₂ , C ₁	Factors for computing limits and process capability
i	Identifier for a specific subgroup

The steps for developing Xbar S charts follow. All averages that are calculated should be rounded to one more decimal place (significant figure) than the values being averaged. The decimal places for the standard deviation should be the same as the averages (note: if using a spreadsheet, rounding is not necessary):

1. Calculate the average, Xbar, for each subgroup (i): $Xbar = \sum X_i / n_i$.
2. Calculate the sample standard deviation for each subgroup:
 - $S = \sqrt{[\sum (X - Xbar)^2 / (n_i - 1)]}$.
3. Calculate the weighted grand average, Xbarbar, the centerline of the Xbar chart:
 - $Xbarbar = \sum (n_i Xbar) / \sum n_i$.
4. Calculate Sbar, the centerline of the standard deviation chart:
 - $Sbar = \sum (n_i S_i) / \sum n_i$.
5. Calculate the limits for each subgroup on the Xbar chart:
 - $UL = Xbarbar + (A_1 * Sbar)$
 - $LL = Xbarbar - (A_1 * Sbar)$

Note: A₁ is a factor that depends on the subgroup size and can be obtained from Table 15A.1.
6. Calculate the limits for each subgroup on the S chart using:
 - $UL = B_1 * Sbar$
 - $LL = B_2 * Sbar$

Note: B₁ and B₂ are factors that depend on the size of the subgroup and can be obtained from Table 15A.1. Note that there is no lower control limit for S when the subgroup size is less than six.

I CHART (FOR INDIVIDUAL VALUES OF CONTINUOUS DATA)

Symbols Associated with I Charts

i	Individual measurement of quality or characteristic
R	The number of individual measures in the data set
MR	The moving range between two adjacent data points
Σ	Summation symbol
MRbar	Average of the moving ranges
Ibar	Average of the individual values. This is the centerline on the chart.

The steps for developing a Shewhart chart for individuals data (k values of the measure I):

1. Calculate the k-1 moving ranges (MR) and the average of these MRs (MRbar)
 - MR for consecutive points i and j = |largest of (i, j) - smallest of (i, j)| = absolute value |I_i - I_j|
 - $MRbar = \sum MR / (k - 1)$.
2. Calculate the upper limit for the MR: $ULMR = 3.27 * MRbar$.
3. Remove any moving range bigger than the ULMR and recalculate the average MR (MRbar).

(Note: This recalculation of the average MR should be done **only once**.)

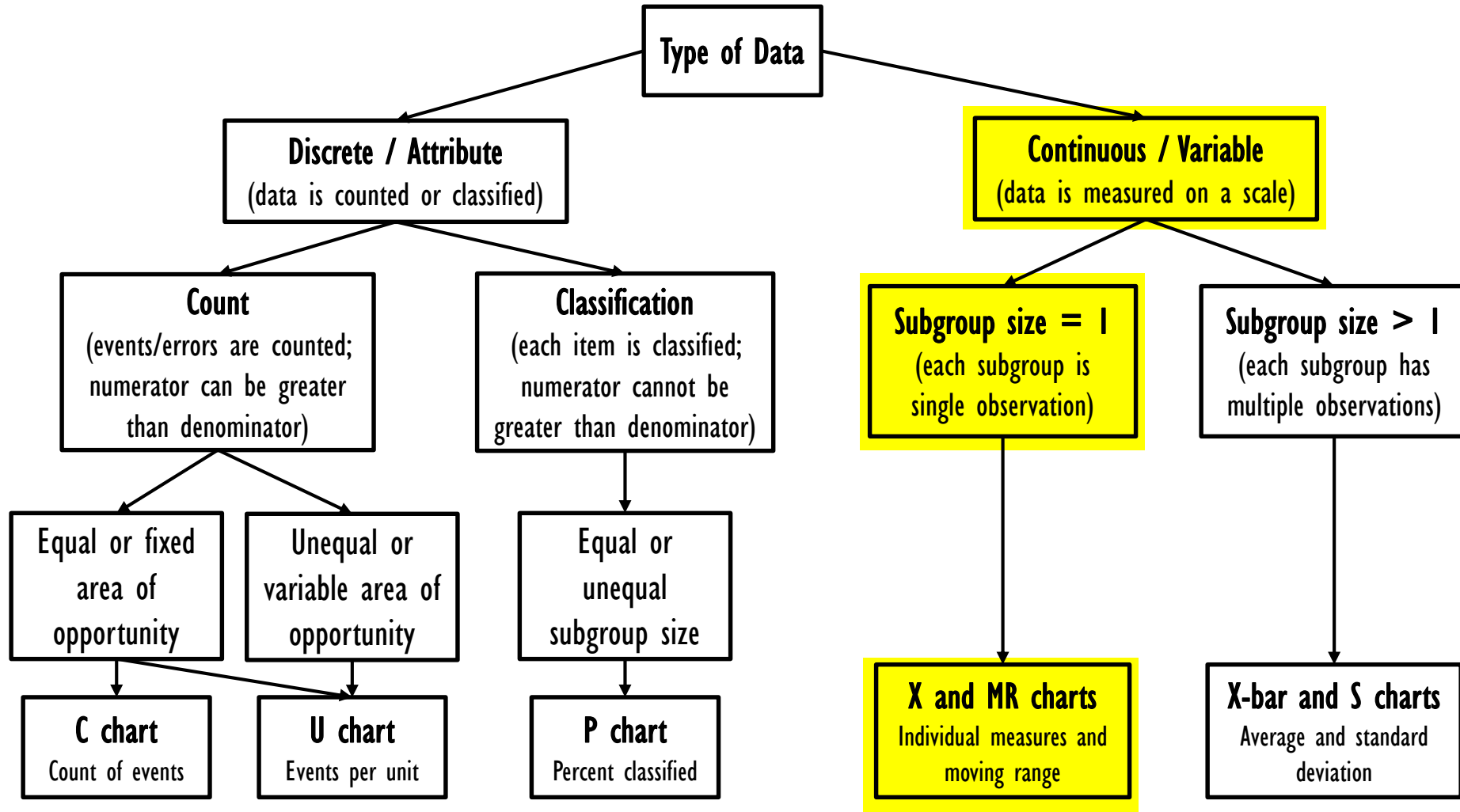
4. Calculate the average of the k measurements (Ibar) to obtain the centerline:
 - $CL = Ibar = \sum I / k$.
5. Calculate the limits for the I chart using:
 - $UL = (Ibar) + (2.66 * MRbar)$
 - $LL = (Ibar) - (2.66 * MRbar)$

Conditions When Skewed Data is Problematic

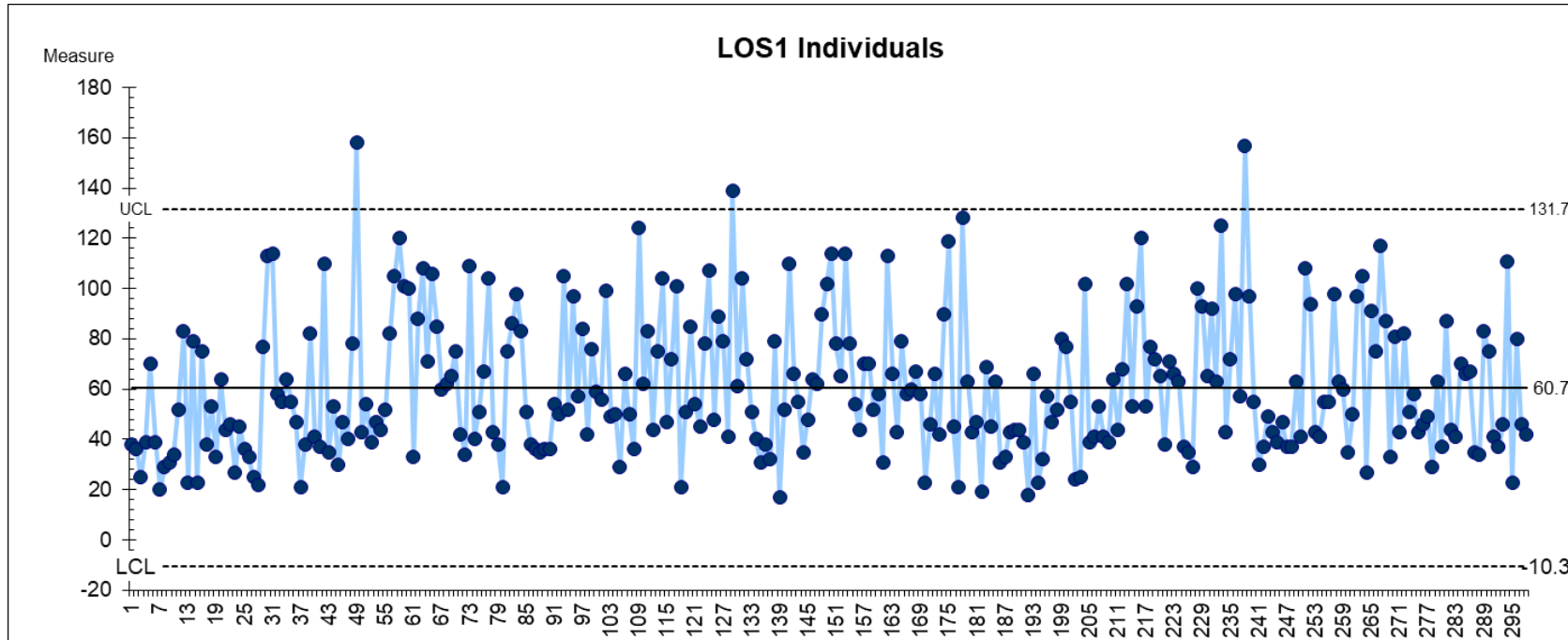
- Conditions when highly skewed data makes interpretation and learning from \bar{X}/S or \bar{X}/mR (I chart) difficult:
 1. The calculated control limit is <0 for a measure where this is not possible
 2. Much more than 50% of the data are below the average
 3. The S-chart has many unexplained special causes occurring due to extreme (but not unexpected) values that occur regularly in a process
 4. There are many false positive signals of special cause variation

Quiz: Determine the Right Chart

You have a small NICU, and you want to examine length of stay for all infants discharged in your unit



LOS: I Chart (X Chart)



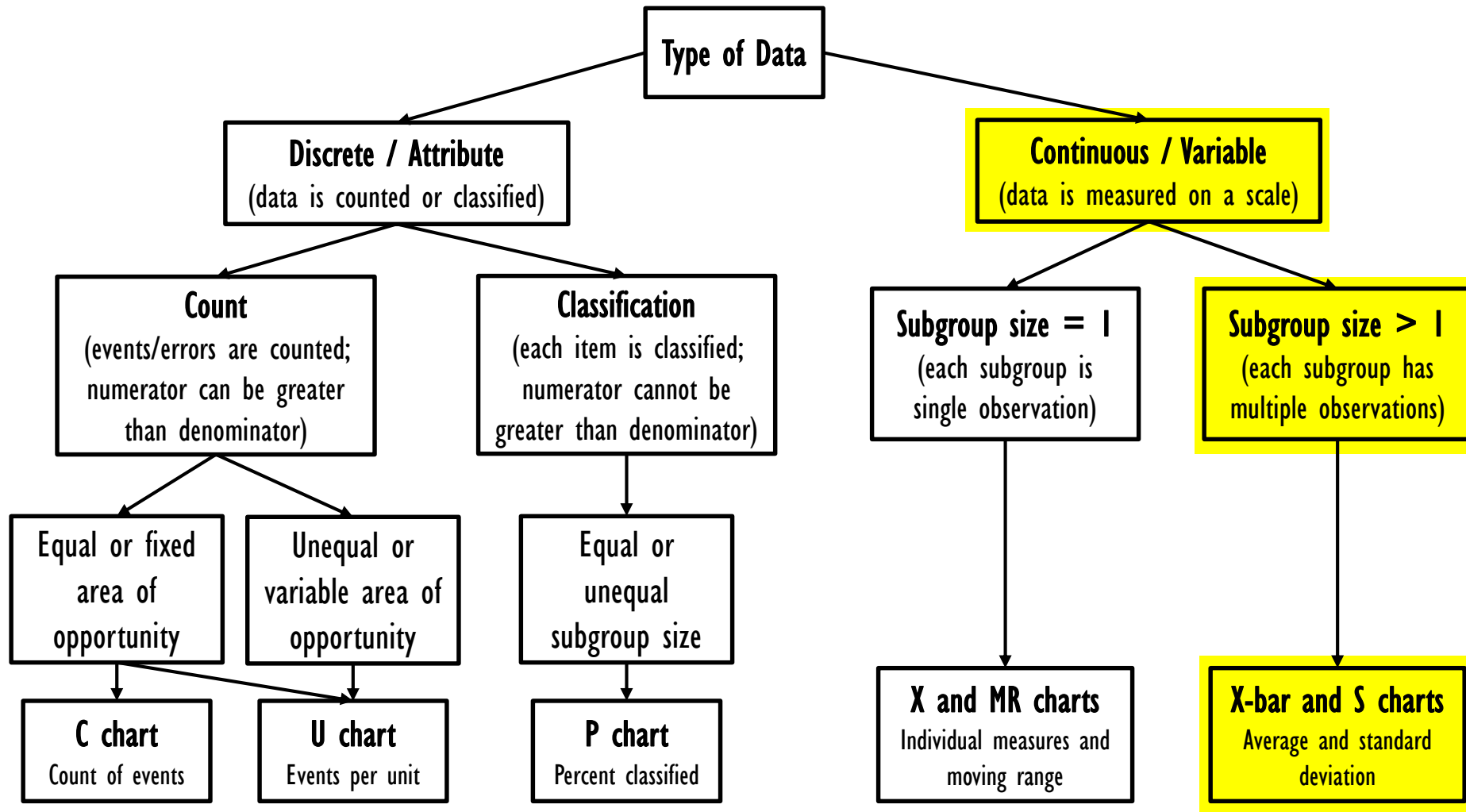
Is the calculated control limit < 0 ? Is this possible?

Does more than 50% of the data fall below the average?

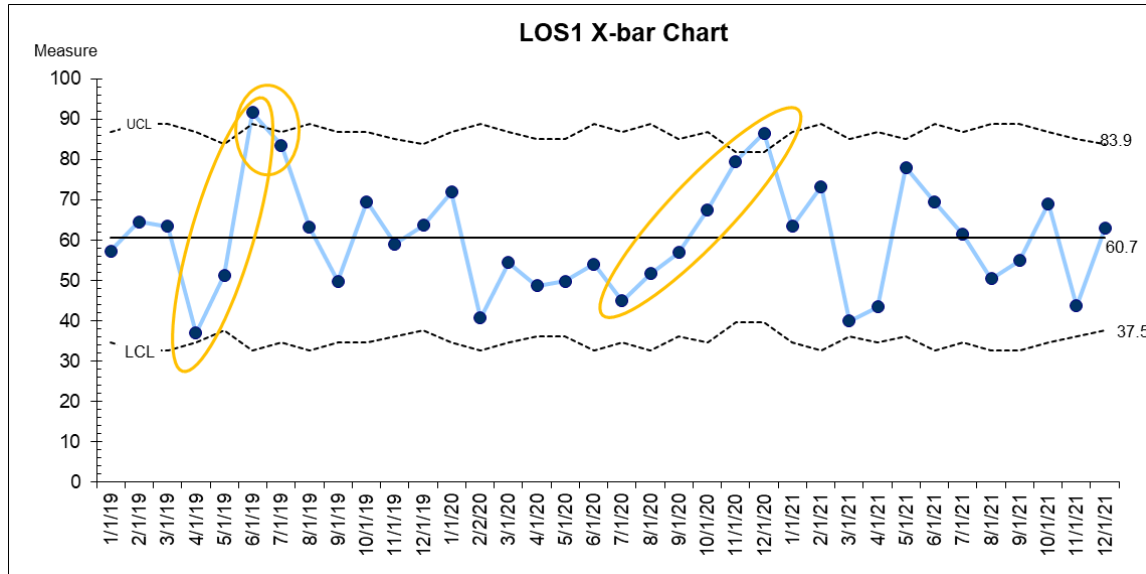
Are there many false positive signals of special cause variation?

Quiz: Determine the Right Chart

You measure the length of stay for all infants discharged in your unit and plot the data monthly



LOS: X-bar/S charts

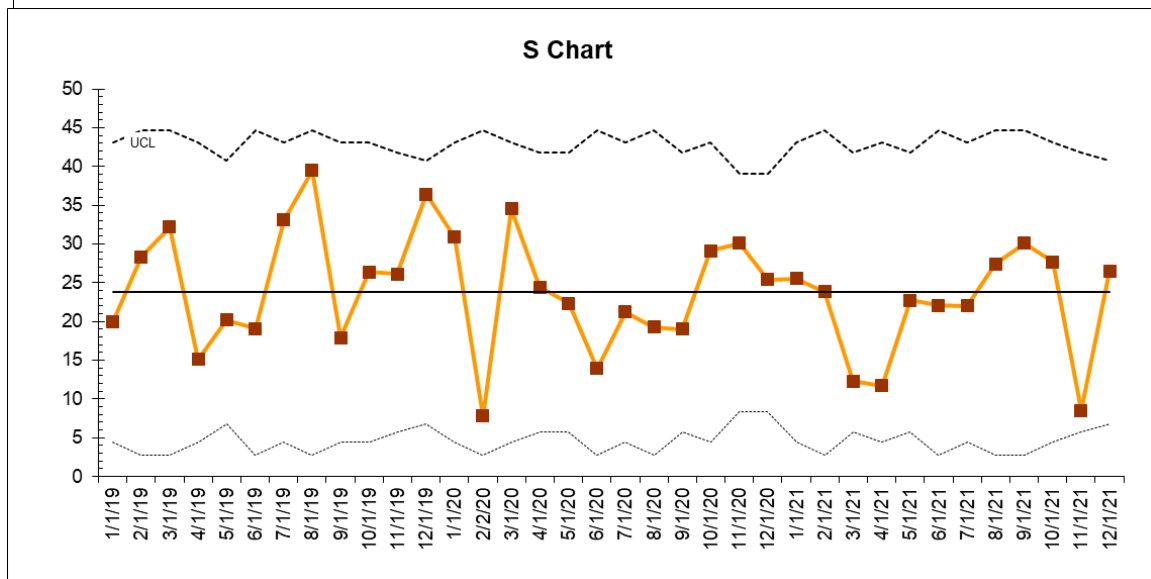


*Is the calculated control limit <0 ?
Is this possible?*

Does much more than 50% of the data fall below the average?

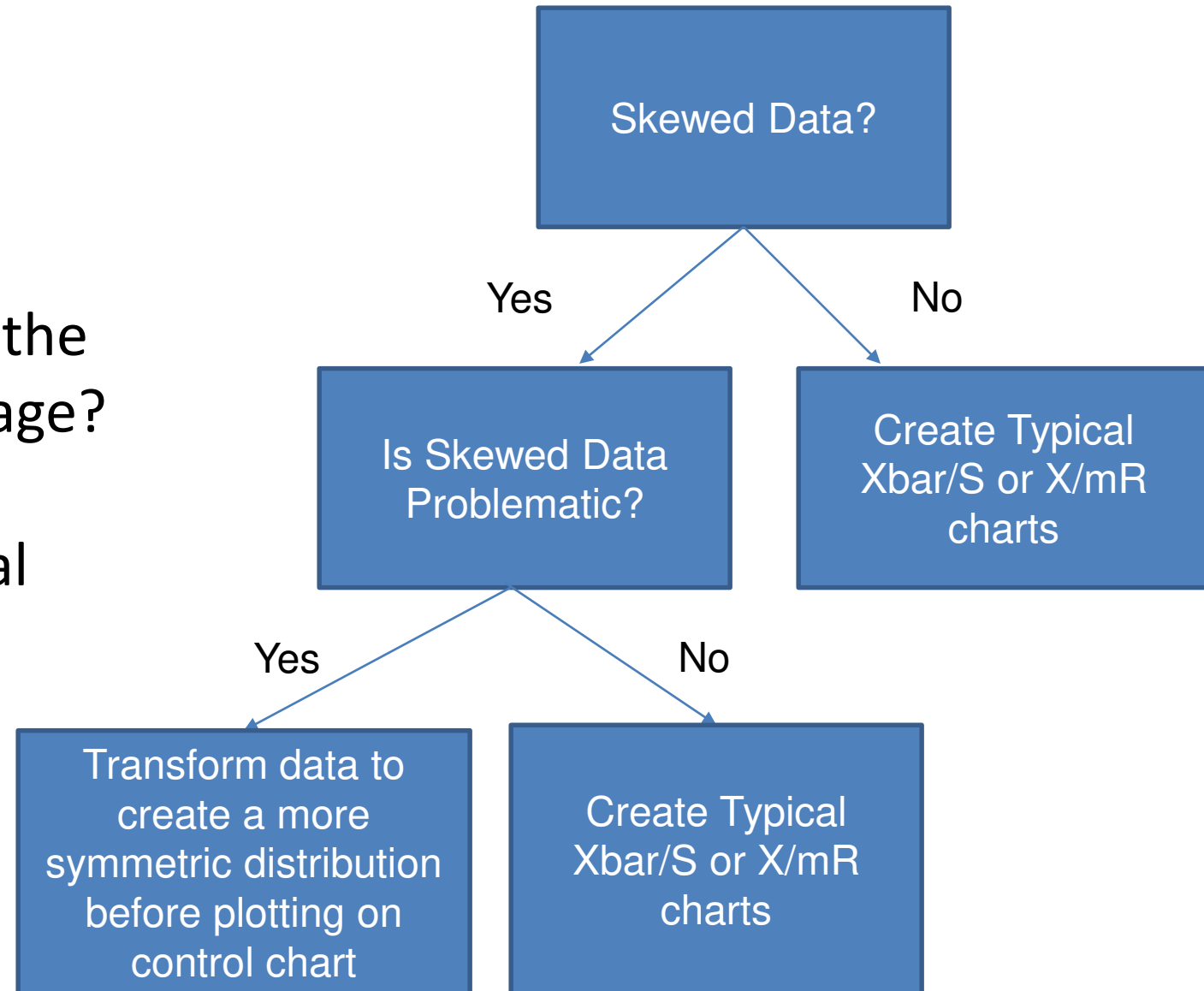
Does the S chart have many unexplained special causes occurring due to extreme (but not unexpected) values that occur regularly in a process?

Are there many false positive signals of special cause variation?

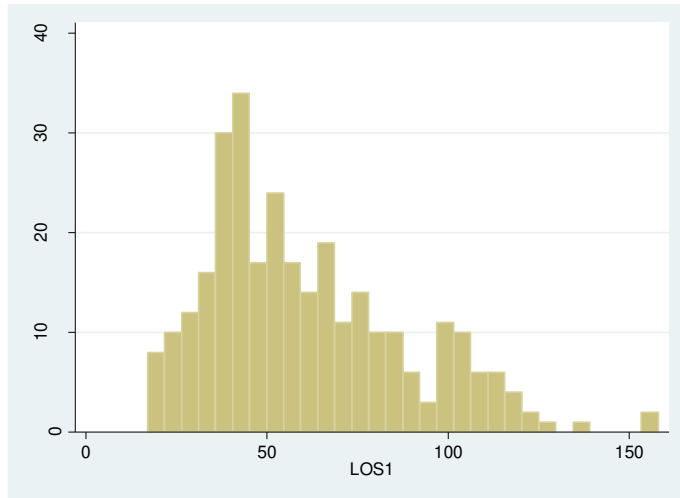


Handling Skewed Data

- Is the calculated control limit <0 ?
- Does more than 50% of the data fall below the average?
- Are there many false positive signals of special cause variation?



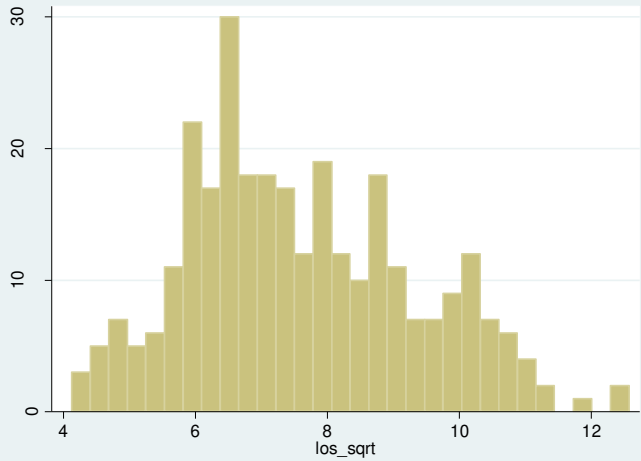
Transformation of NICU LOS Data



Non-transformed

Mean: 60.695

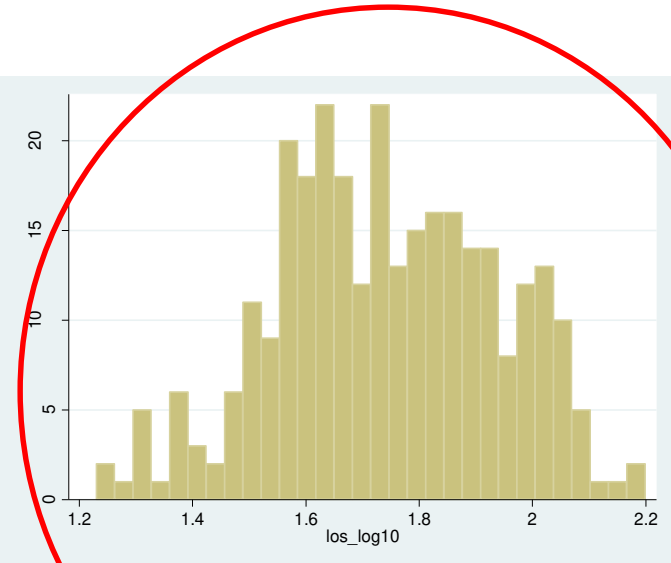
Median: 54



Square Root

Mean: 7.6

Median: 7.35



Log10

Mean: 1.74

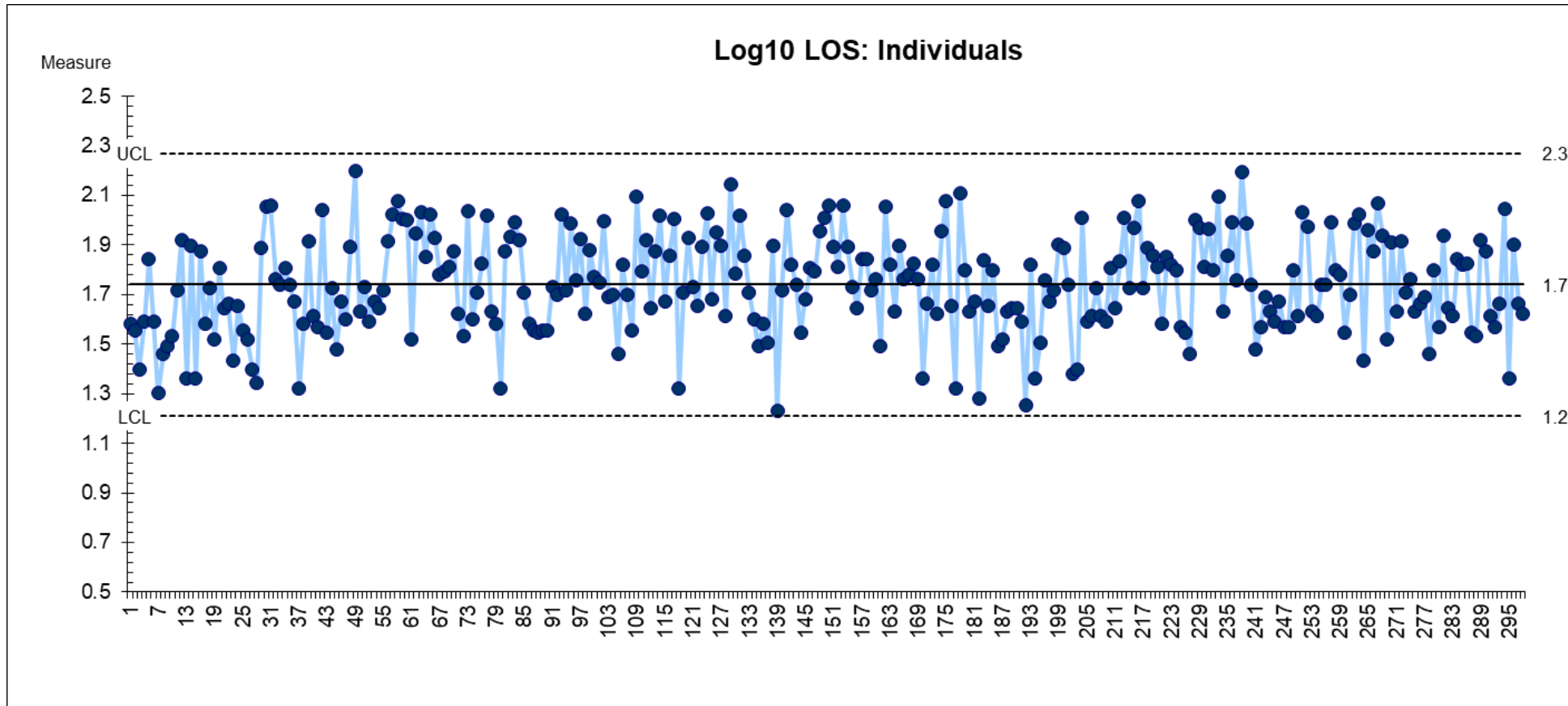
Median: 1.732

*Which transformation appears most symmetric?
Which transformation results in closest mean and median?*

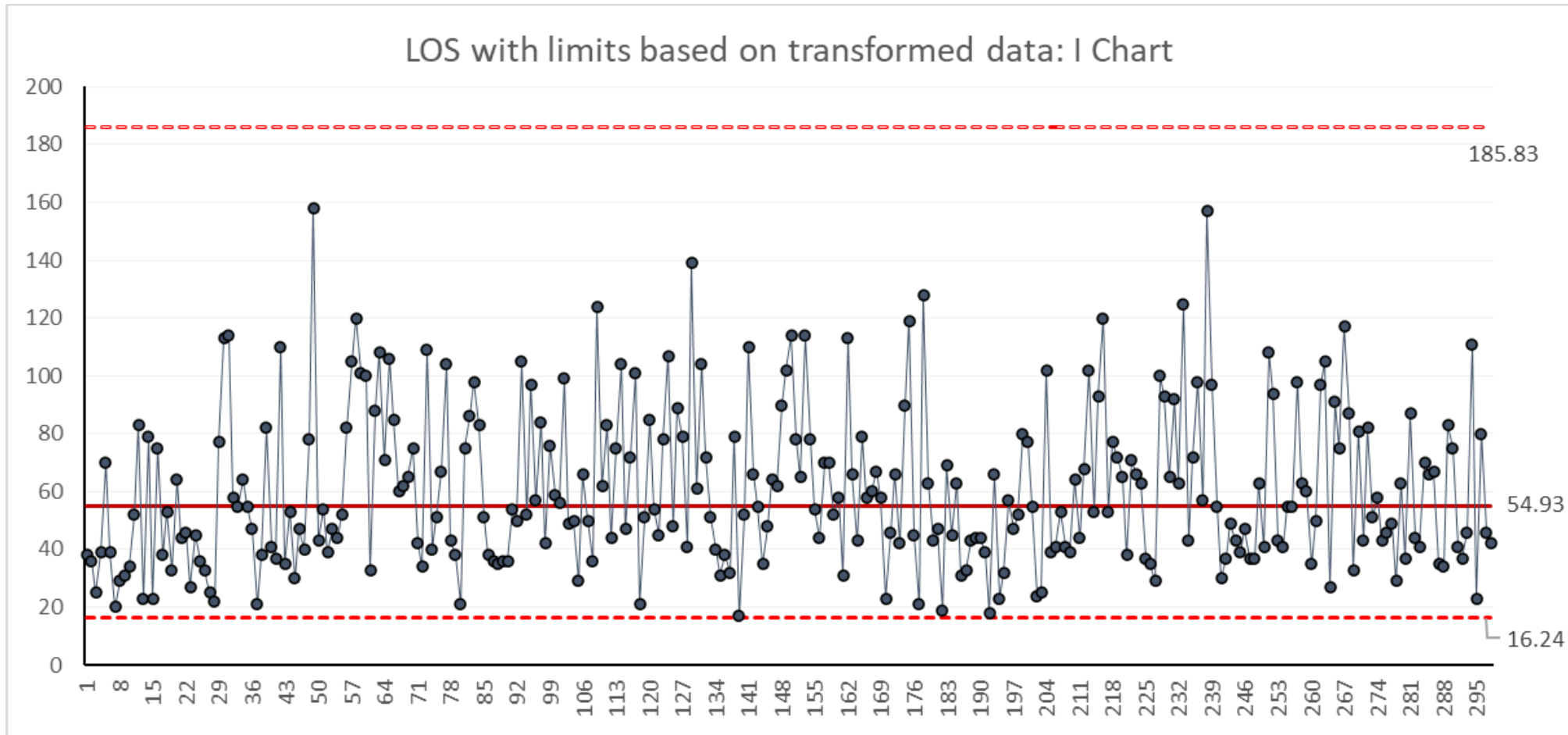
Creating Control Charts with Transformed Data

	Original Data (I chart)			
	Data Point	CL	UCL	LCL
1	38	60.7	131.7	-10.3
2	36	60.7	131.7	-10.3
3	25	60.7	131.7	-10.3
4	39	60.7	131.7	-10.3
5	70	60.7	131.7	-10.3
6	39	60.7	131.7	-10.3
7	20	60.7	131.7	-10.3
8	29	60.7	131.7	-10.3

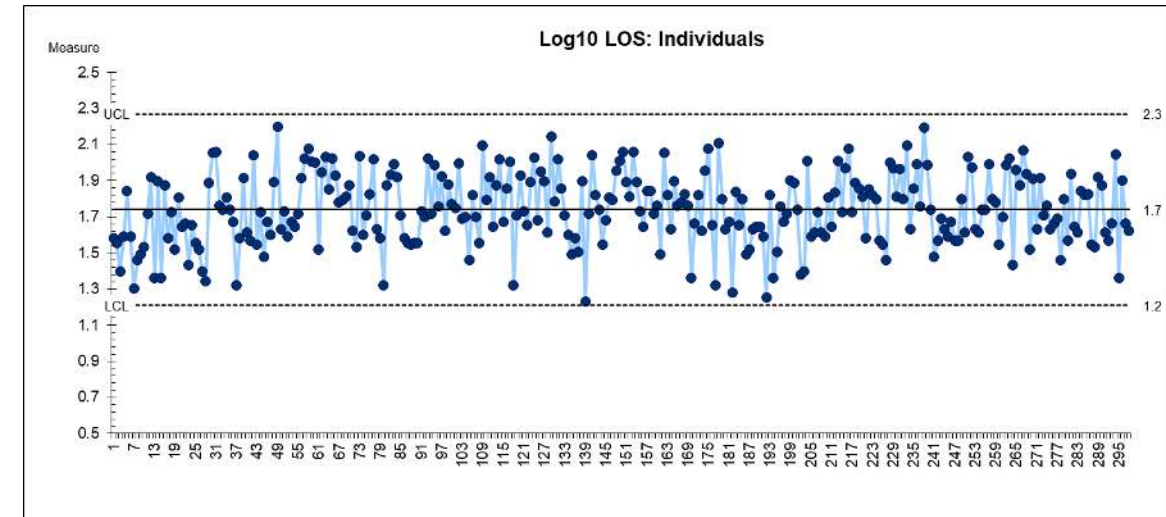
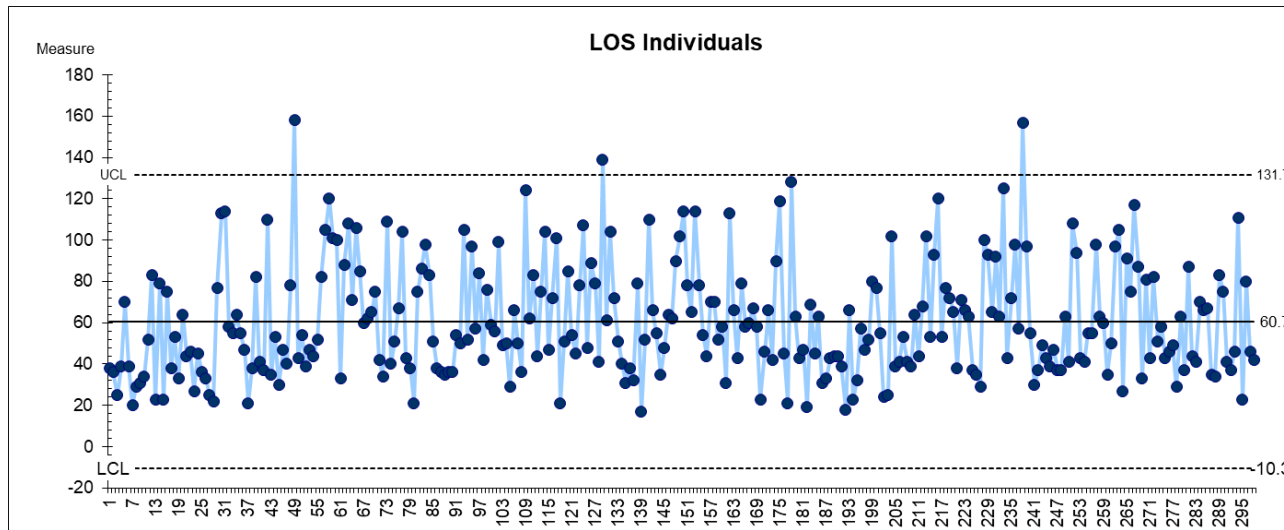
Creating Control Charts with Transformed Data



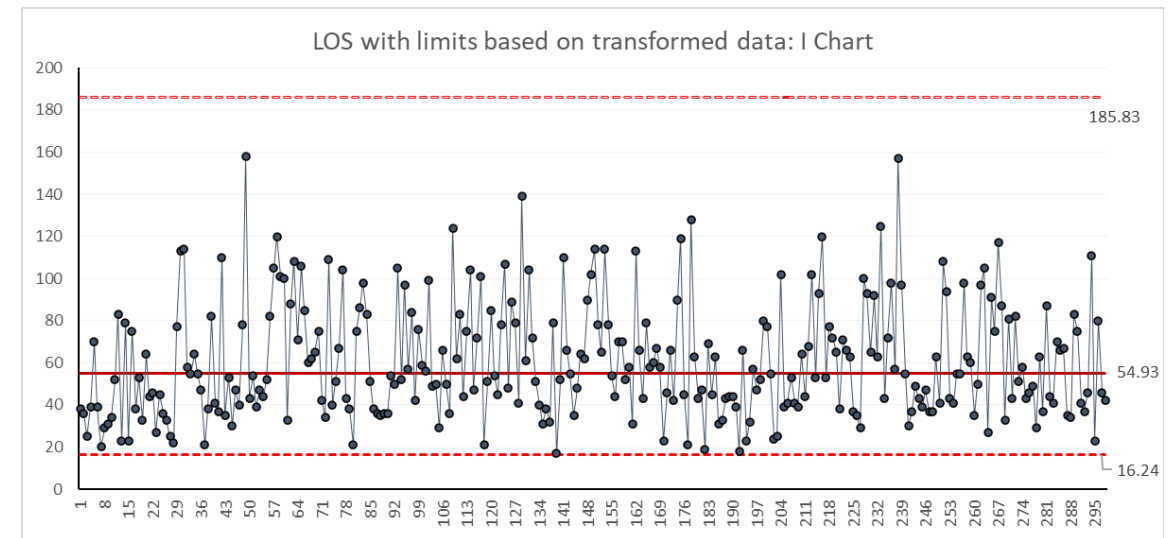
Creating Control Charts with Transformed Data



Comparing Transformed and Non-Transformed I Charts



The I chart has multiple “false” special cause signals on non-transformed that are no longer present on the transformed chart



Summary: Skewed Data

- If continuous data are skewed try to use X-bar and S charts with large subgroup sizes. These charts are less sensitive to skewed distributions than I charts (XmR charts).
 - If your data is skewed with evidence of false positive special cause signals on either the S chart or I chart, transform the data to create a more symmetric distribution and more helpful control chart
 - While transformation of data and creation of a control chart using transformed data can be done manually to enable creation of charts in SPC programs, it can be helpful to engage with a data analyst or statistician if this is necessary.
-


Example in the Published Literature

Journal of Perinatology (2021) 41:164–172
<https://doi.org/10.1038/s41372-020-0768-0>

QUALITY IMPROVEMENT ARTICLE



A quality improvement project improving the value of iNO utilization in preterm and term infants

Hannah Fischer ¹ · Tamina Singh¹ · Lori Devlin¹ · Olugbemisola Obi¹ · Tonya Robinson¹ · Seth Schultz¹ · Sucheta Telang¹ · Scott Duncan¹

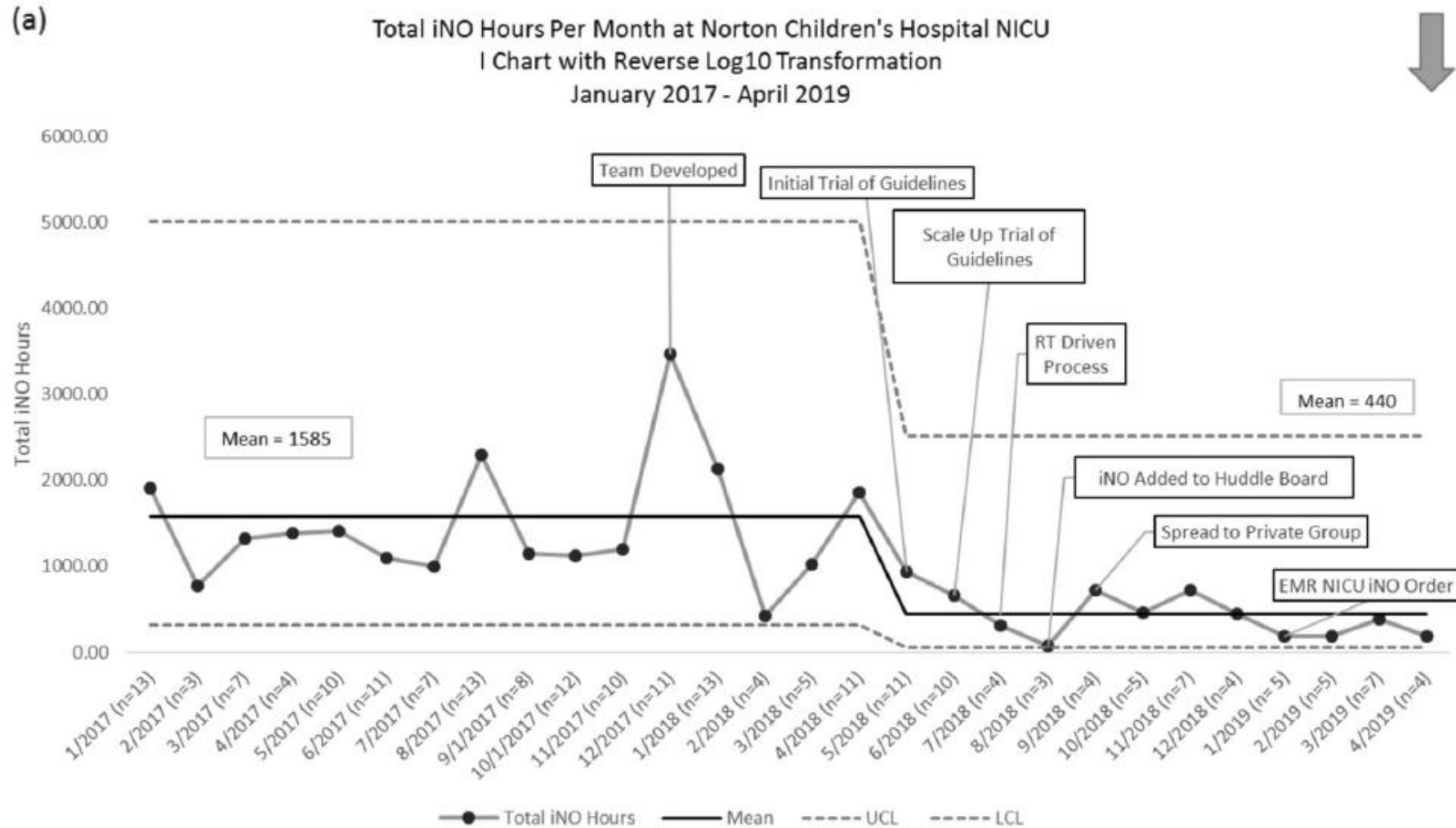
Example in the Published Literature (cont'd)

Measures and analysis

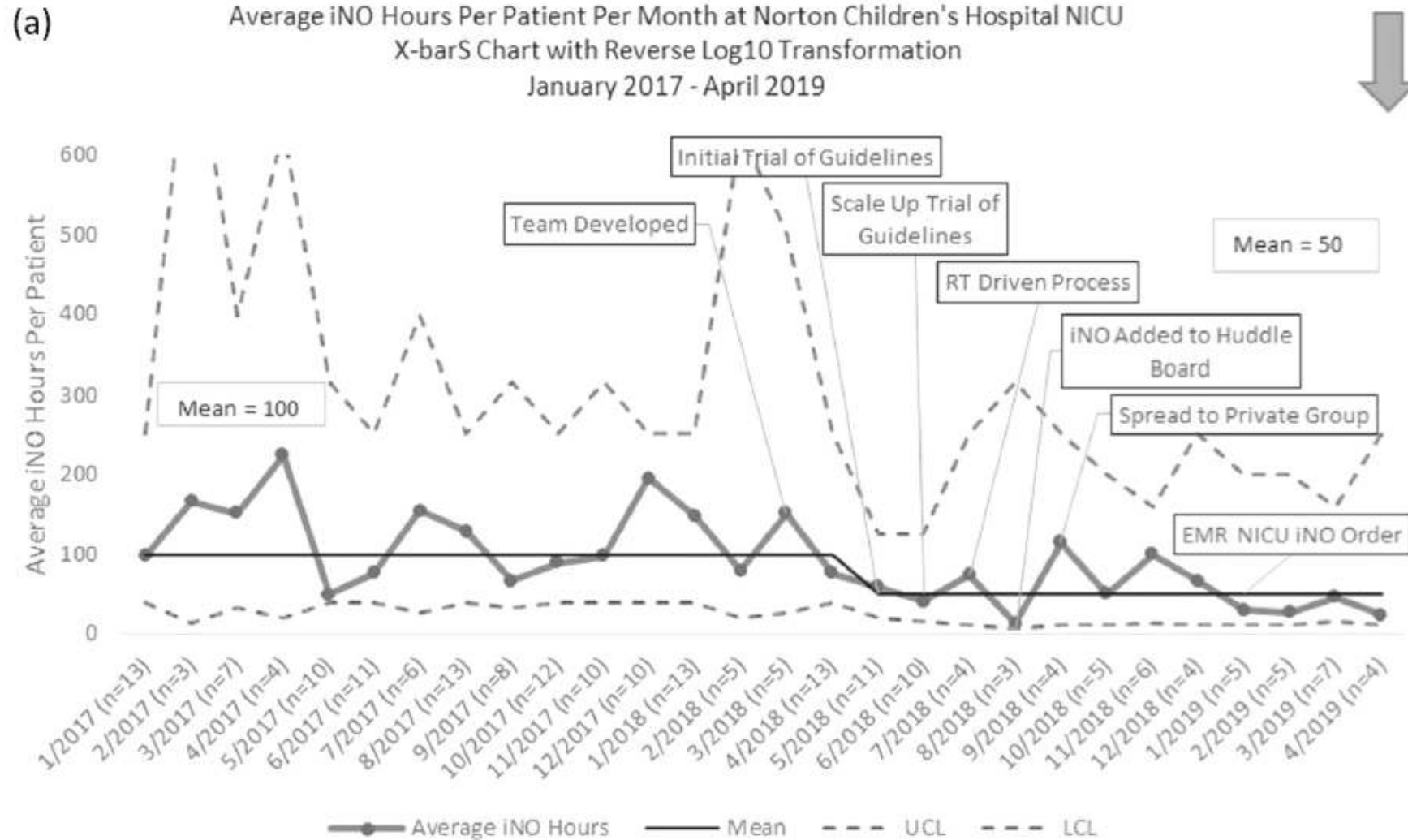
Baseline data were collected from January 2017 to April 2018 from an existing database maintained by unit RTs, including month/year, hours of iNO per patient, gestational age at time of iNO initiation, and indication for iNO. Infants with a diagnosis of congenital diaphragmatic hernia were excluded from our data set, as iNO use in this population is directed by our NICU pulmonary hypertension team. Infants > 34 weeks gestational age at birth were considered term. Infants born \leq 34 weeks were considered preterm until a corrected age of 40 weeks, at which time they were considered term. During data analysis, patients were assigned to the month based on the date iNO was initiated. Total iNO hours per month, average iNO hours per patient per month and the percentage of infants with iNO course >120 h were calculated and stratified by gestational age. We chose >120 h as a prolonged course based on opinion that reversible causes of pulmonary hypertension should improve within this time period.

(Version 2.0.23) and Microsoft Excel (Version 16.16.4). Since the data for the measures were highly skewed and covered three orders of magnitude, a log₁₀ transformation was used for the control chart analysis and the limits transformed back to hours when displaying the charts [18]. The baseline control limits and mean for each chart were calculated using data from January 2017 to April 2018. Rules for special cause variation were utilized for evaluation, including eight data points above or below the centerline to indicate a shift, six down trending or up trending points to indicate a trend, and two consecutive points near a control limit or one point outside a control limit as evidence of special cause variation [18]. New control limits and centerline were calculated if these signals were observed and the data pattern indicated new performance.

Example in the Published Literature (cont'd)



Example in the Published Literature (cont'd)



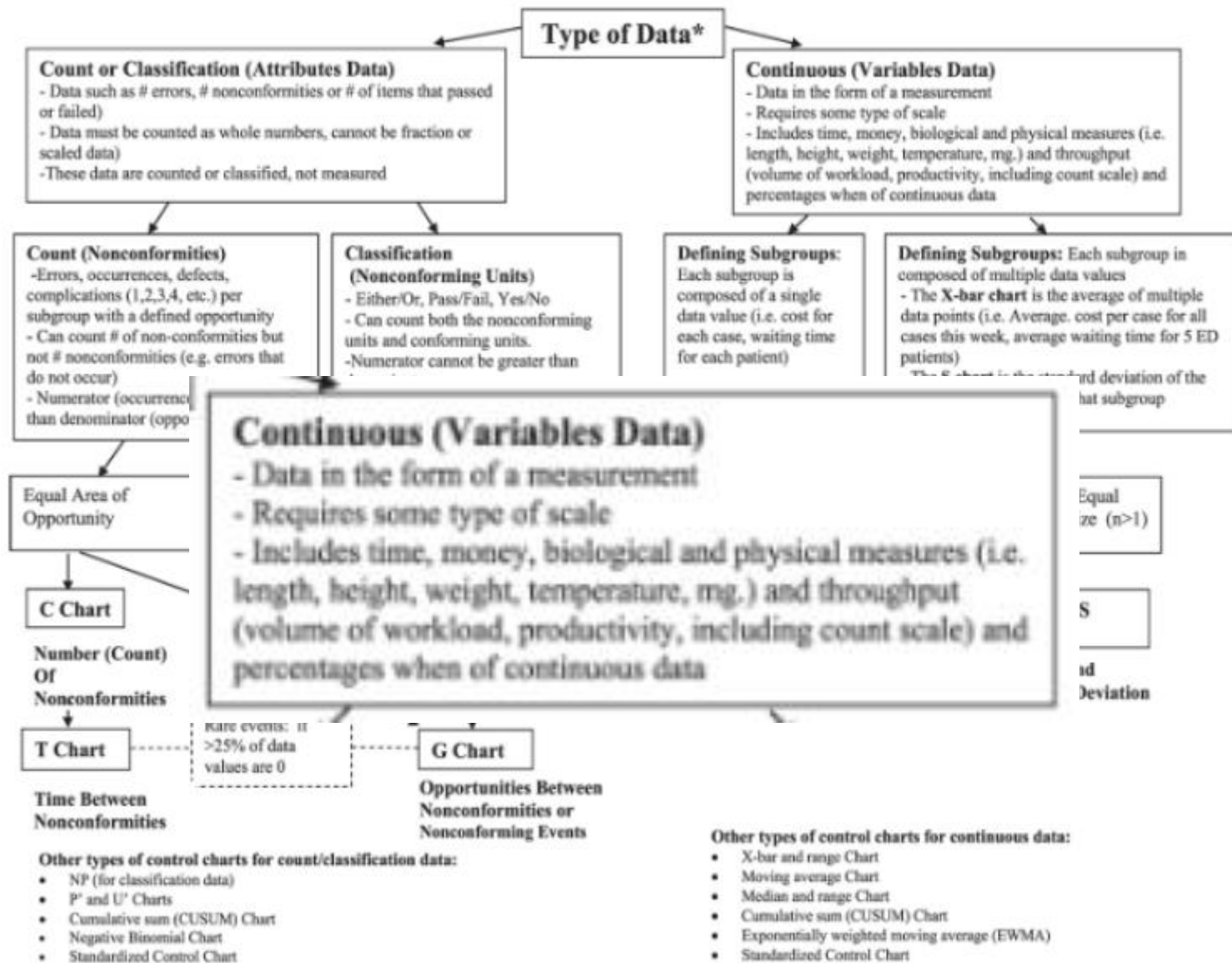
Skewed Data

Hands-On Examples!

Three Topics

- Fixing and changing the centerline and control limits
 - Non-symmetrically distributed (highly skewed) continuous data
 - **Count as continuous data**
-

Shewhart Chart Selection Guide



*A run chart may be used with any type of data. It is often the starting point for viewing data over time when little data are available.

*Typical **continuous data** include biologic measures, time, financial, physical measures, perception data recorded on a scale (for example, Likert scale), or throughput (workload, productivity). In health care, workload or productivity often use a numeric scale (for example, number of patients admitted, number of clinic visits, number of resident days, and number of childhood immunizations provided in the country). Although the numerical scale for workload data and Likert scales for perception data yield discrete data (data that are whole numbers when collected), they are still best treated as continuous data when using Shewhart charts.*

- Health Care Data Guide, 2nd ed, page 160

Attribute Charts

- In attribute charts, ONE parameter (mean) describes both central tendency and dispersion of the data.
 - Dispersion is theoretical, based on expected distribution (binomial for P-charts, Poisson for U- and C-charts).
 - **This assumes that the events being measured have a consistent likelihood of occurring.**
-

Workload or Production Measures

- Attribute charts were originally developed to measure **defects** – unexpected events where the chance of them happening was similar throughout sample period.
 - Measures of workload or production typically examine events that are **expected** to happen.
 - Most likely, the probability of these events NOT happening is unlikely to be consistent throughout the sample period.
-

How to tell something's off

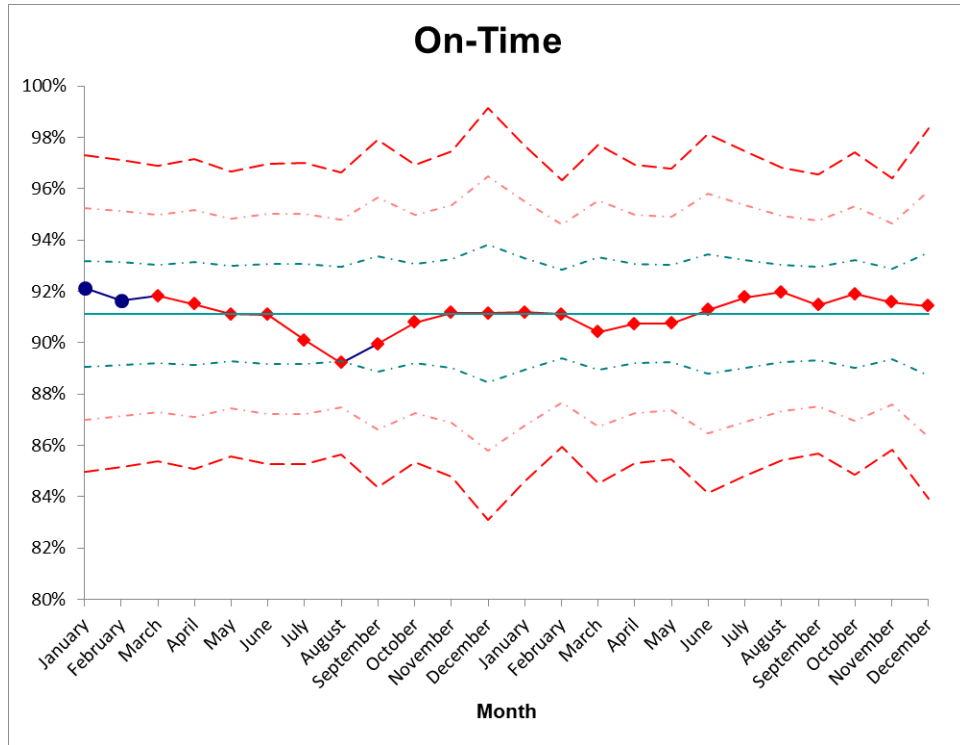
- In cases where discrete data are not following typical binomial or Poisson distributions, attribute control charts will show unusual data patterns, such as:
 - Wide control limits with data points clustered around center-line; or
 - Narrow control limits with many data points beyond the outer limits.
-

Example

The Proportion of On-Time Shipments

Month	Year	Total No.	No. On-Time	On-Time %	Month	Year	Total No.	No. On-Time	On-Time %
January	01	191	176	92.1	January	02	170	155	91.2
February	01	203	186	91.6	February	02	270	246	91.1
March	01	220	202	91.8	March	02	167	151	90.4
April	01	200	183	91.5	April	02	216	196	90.7
May	01	236	215	91.1	May	02	227	206	90.7
June	01	213	194	91.1	June	02	149	136	91.3
July	01	212	191	90.1	July	02	182	167	91.8
August	01	241	215	89.2	August	02	224	206	92.0
September	01	159	143	89.9	September	02	246	225	91.5
October	01	217	197	90.8	October	02	185	170	91.9
November	01	181	165	91.2	November	02	261	239	91.6
December	01	113	103	91.2	December	02	140	128	91.4

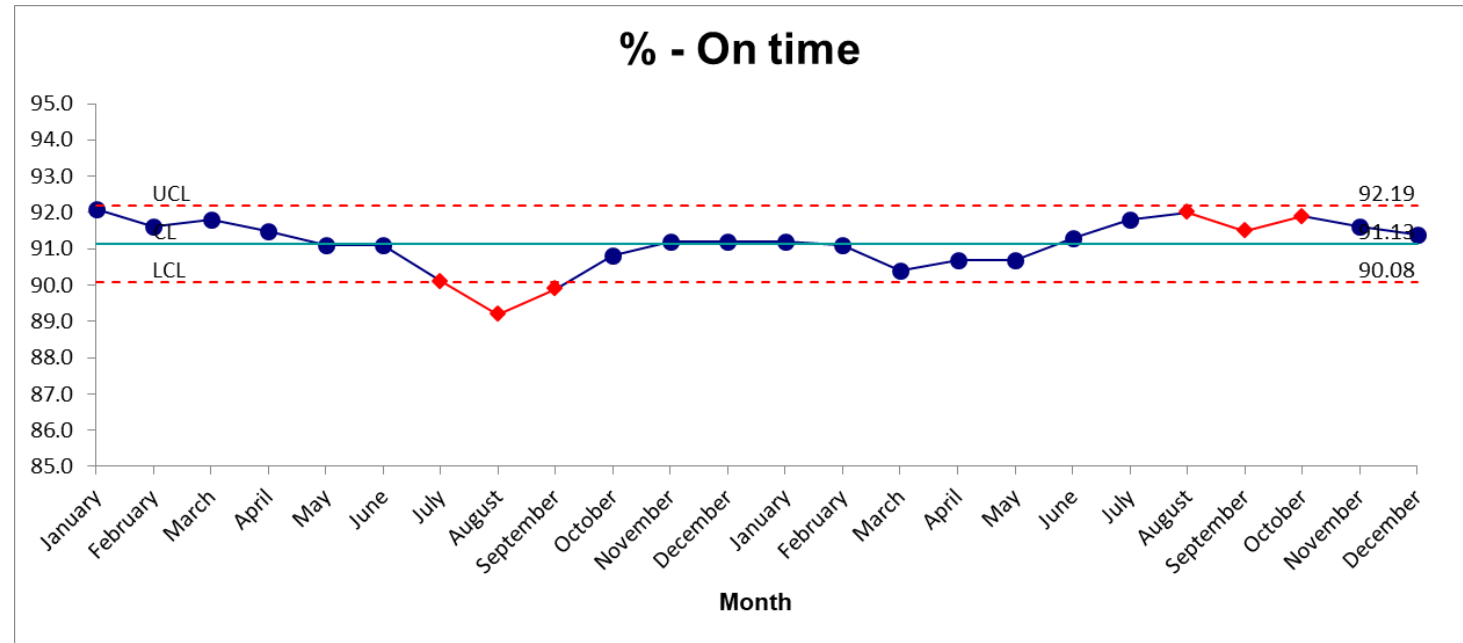
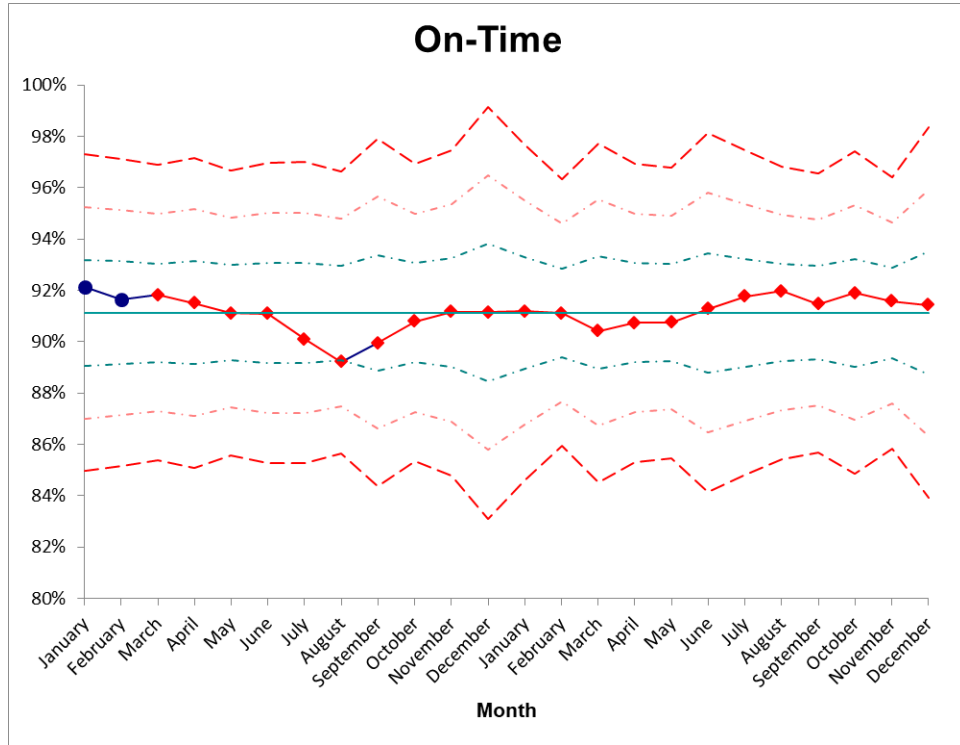
Example



Suggested Alternative Approach

- Consider count data continuous , and use I-chart (XmR).
 - Limits are calculated based on measured variation in data and will more accurately identify common and special cause variation.
 - I-chart can be constructed using each sample's value as individual data point (e.g., monthly proportion or rate).
-

Example



Real Examples

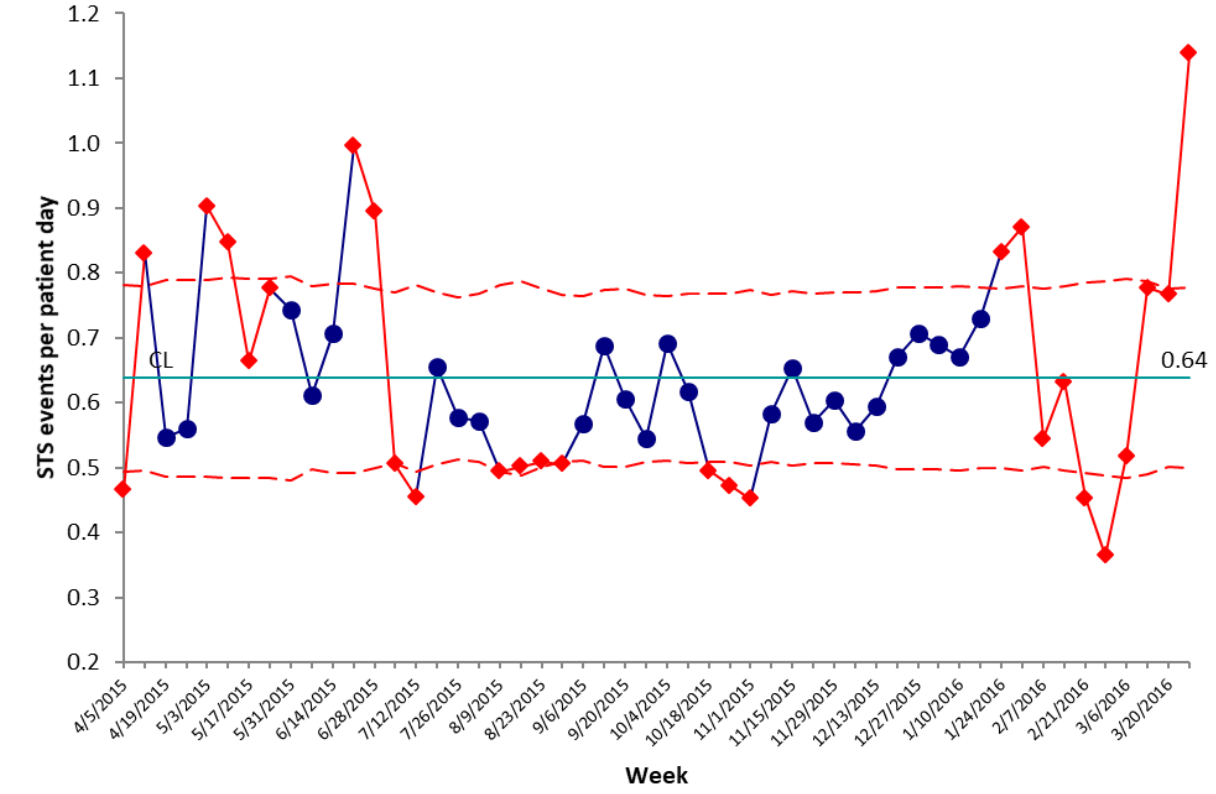
- Skin-to-skin in NICU
 - Antibiotic utilization rates
-

Example: Skin-to-Skin Events in NICU

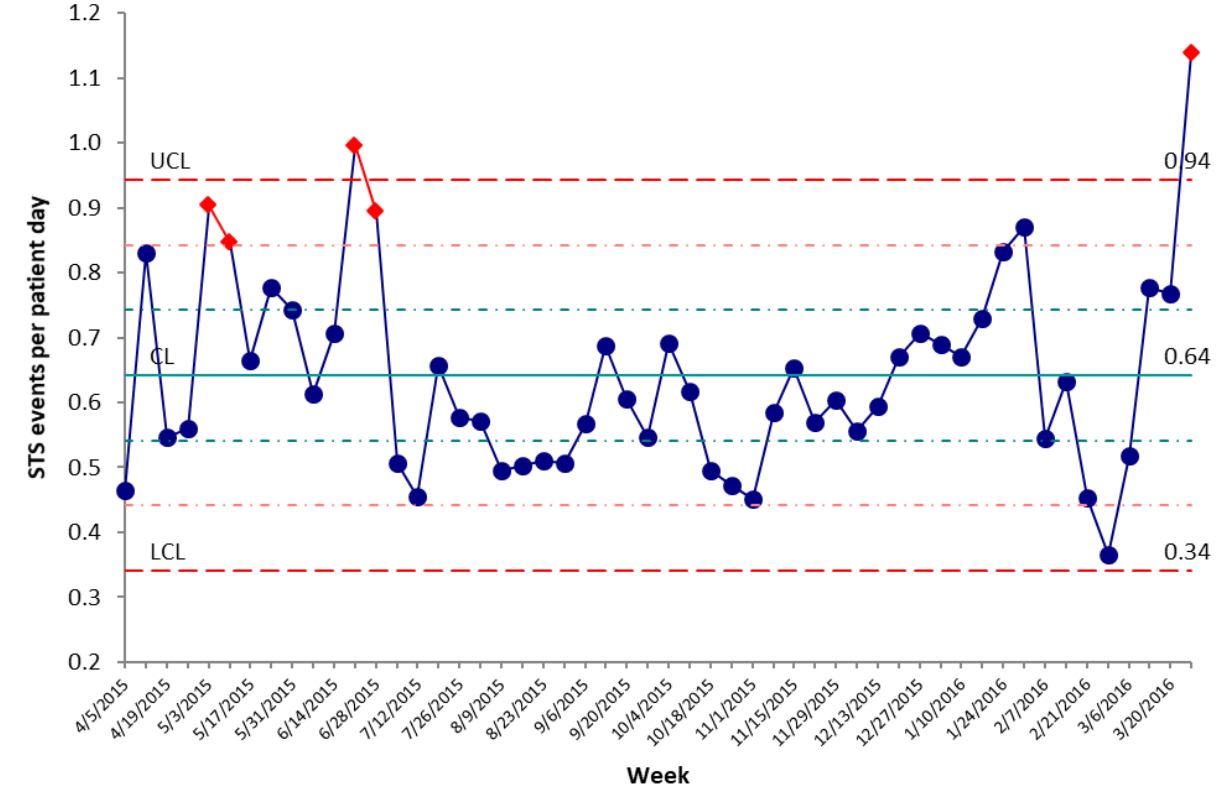
Week	Patient Days	STS Events	Week	Patient Days	STS Events
4/5/2015	275	128	10/4/2015	354	245
4/12/2015	283	235	10/11/2015	334	206
4/19/2015	249	136	10/18/2015	343	170
4/26/2015	250	140	10/25/2015	341	161
5/3/2015	248	224	11/1/2015	314	142
5/10/2015	241	204	11/8/2015	346	202
5/17/2015	244	162	11/15/2015	320	209
5/24/2015	246	191	11/22/2015	335	191
5/31/2015	233	173	11/29/2015	333	201
6/7/2015	289	177	12/6/2015	329	183
6/14/2015	270	191	12/13/2015	316	188
6/21/2015	272	271	12/20/2015	294	197
6/28/2015	302	270	12/27/2015	293	207
7/5/2015	332	168	1/3/2016	290	200
7/12/2015	277	126	1/10/2016	285	191
7/19/2015	329	216	1/17/2016	296	216
7/26/2015	371	214	1/24/2016	298	248
8/2/2015	341	195	1/31/2016	287	250
8/9/2015	275	136	2/7/2016	305	166
8/16/2015	257	129	2/14/2016	286	181
8/23/2015	304	155	2/21/2016	267	121
8/30/2015	344	174	2/28/2016	255	93
9/6/2015	361	205	3/6/2016	243	126
9/13/2015	308	212	3/13/2016	260	202
9/20/2015	305	185	3/20/2016	305	234
9/27/2015	348	190	3/27/2016	296	337

Example: Skin-to-Skin Events in NICU

**Skin-to-skin events in NICU
u-chart (weekly)**



**Skin-to-skin events in NICU
I chart (weekly)**

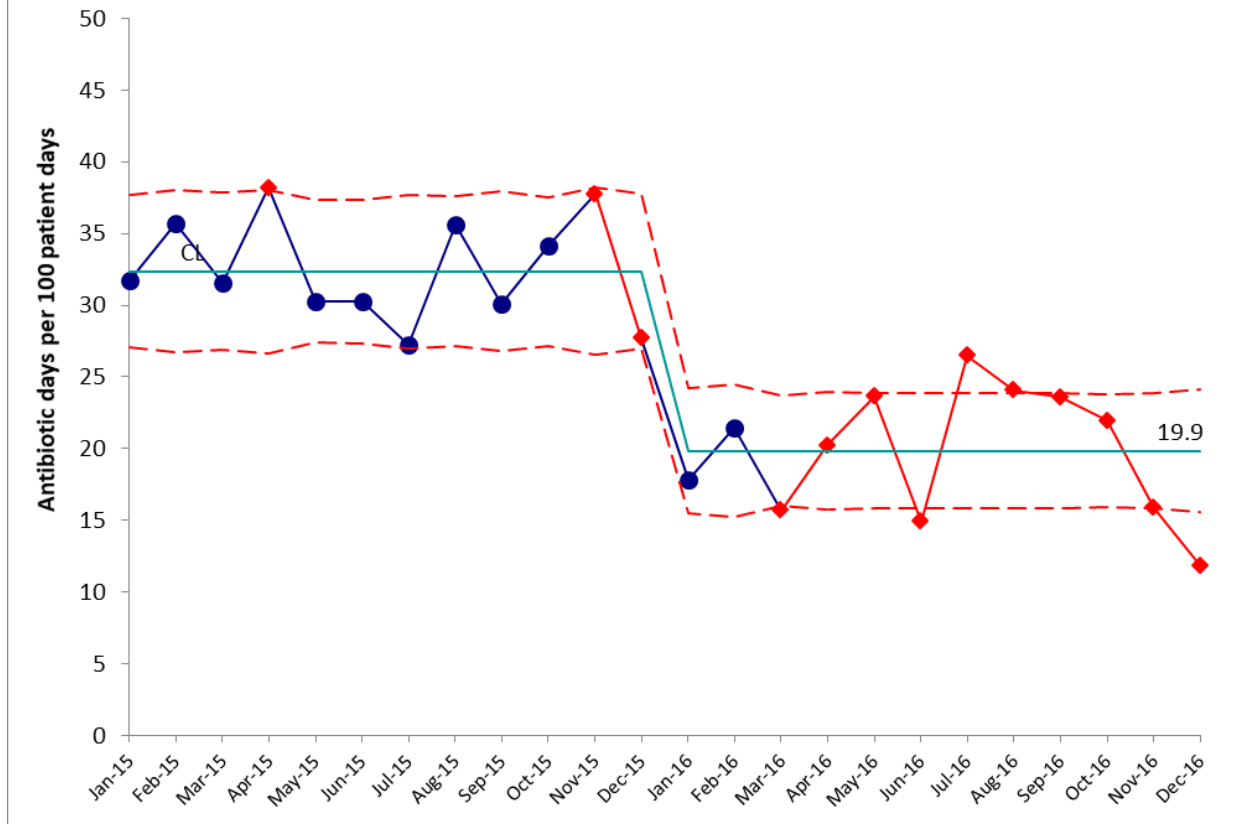


Example: AUR in NICU

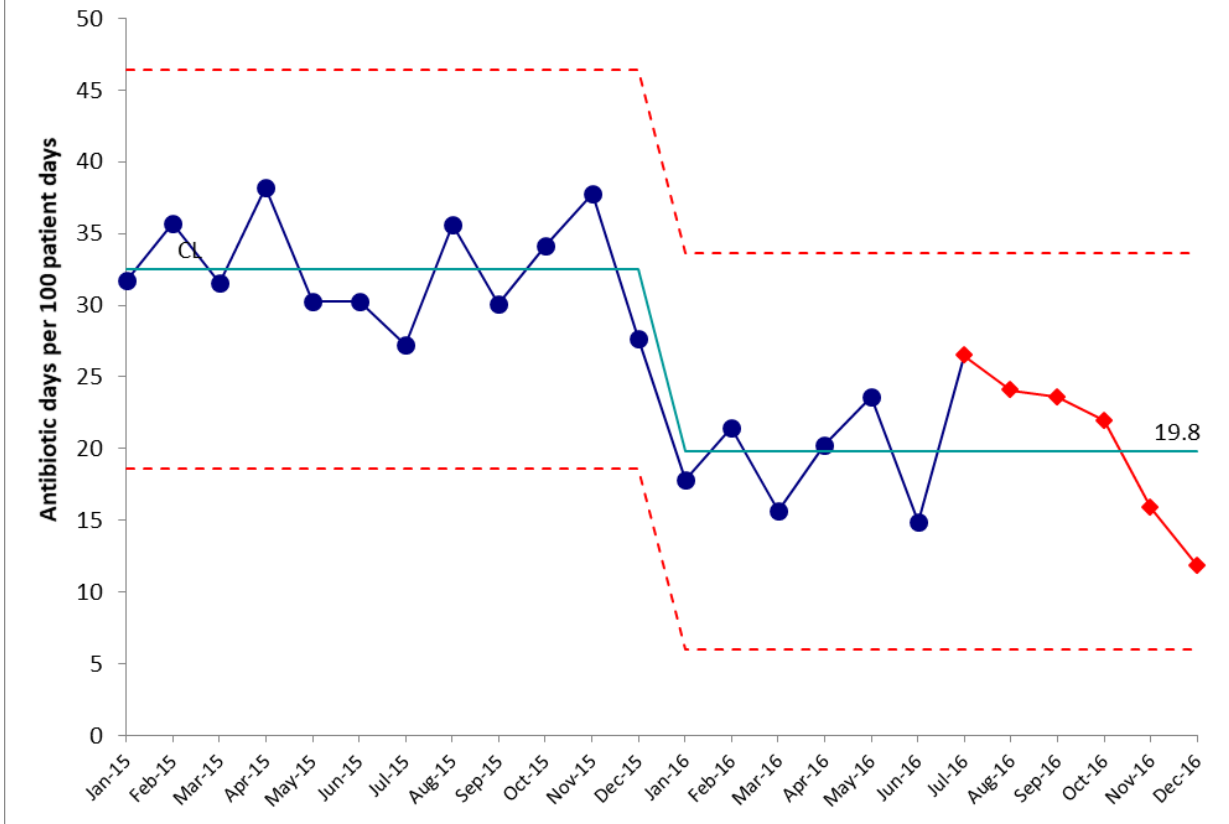
Month	Antibiotic days	Patient Days
Jan-15	327	1032
Feb-15	327	915
Mar-15	304	964
Apr-15	344	901
May-15	358	1184
Jun-15	352	1164
Jul-15	276	1013
Aug-15	378	1061
Sep-15	282	936
Oct-15	368	1079
Nov-15	324	858
Dec-15	278	1004
Jan-16	169	948
Feb-16	177	824
Mar-16	190	1210
Apr-16	215	1063
May-16	259	1095
Jun-16	162	1088
Jul-16	300	1132
Aug-16	271	1126
Sep-16	258	1093
Oct-16	259	1179
Nov-16	177	1116
Dec-16	118	995

Example: AUR in NICU

Antibiotic Utilization Rate in NICU u-chart



Antibiotic Utilization Rate in NICU I chart



Why not always I-charts?

In contrast to this use of theoretical models which may or may not be correct, the XmR Chart provides us with empirical limits that are actually based upon the variation present in the data. This means that you can use an XmR Chart with count based data anytime you wish. Since the p -chart, the np -chart, the c -chart, and the u -chart are all special cases of the chart for individual values, the XmR chart will mimic these specialty charts when they are appropriate and will differ from them when they are wrong.

Wheeler DJ, So You Want to Use a p-Chart?, Quality Digest Daily, 2021

Why not always I-charts?

- I-charts are generally less sensitive than attribute charts for less frequent events.
- I-charts do not account for differences in sample size from point to point, which can influence understanding.
- I-charts are more sensitive to skewed data.

Summary: Count Data as Continuous

- Most discrete measures should be considered attribute data and analyzed using P-charts, U-charts, and C-charts.
 - For measures of productivity or workload, where events are not infrequent but rather are planned and expected to happen, consider using I-charts of individual data points, particularly if attribute charts show control limits that seem inappropriately wide or narrow.
 - (Make sure special cause isn't real!)
-

Count as Continuous Data

Hands-On Examples!



Take Home Points

- Use time-series SPC data analysis for QI!
 - Think about fixing and updating center lines and limits (appropriately!) to maximize learning from your data.
 - Look at symmetry of continuous data and transform skewed data that is impacting learning.
 - Think about using continuous charts for discrete data that doesn't seem right on attribute charts.
-

References

- Gupta M, Kaplan HC. Using Statistical Process Control to Drive Improvement in Neonatal Care: A Practical Introduction to Control Charts. *Clin Perinatol*. 2017;44(3):627-44.
- Provost LP, Murray SK. *The Health Care Data Guide*. John Wiley & Sons, Hoboken NJ. 2nd edition, 2022.
- Wheeler DJ. So you want to use a p-chart. *Quality Digest Daily*. October 4, 2021. Manuscript 389.
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- Gupta M, Provost LP, Kaplan HC. Challenging Cases in Statistical Process Control for Quality Improvement in Neonatal Care. *Clin Perinatol*. 2023;50(2):321-341.

Thank you!

**Please complete the
evaluation!**

