Statistical Concepts in Quality Improvement

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July 28, 2016

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- We have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.
- We do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Objectives

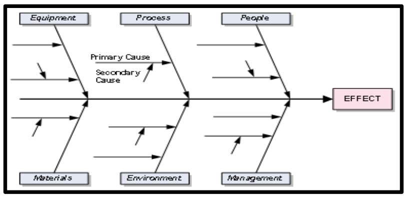
- Review basic statistical measures of central tendency and variation and differences between their application in clinical research and improvement science
- Gain familiarity with a variety of charts and statistical techniques for display and analysis of the types of data commonly used in quality improvement (QI)
- Apply these concepts in the graphical presentation and analysis of data using a test dataset and publically available EXCEL macros

Agenda

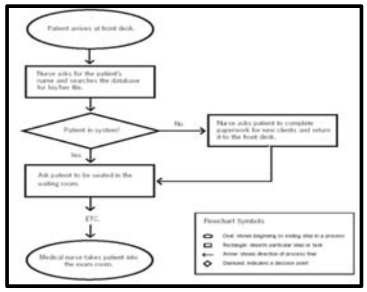
- Origin of statistical process control (SPC)
- History of SPC in healthcare
- Review of basic statistics
  - Measures of central tendency and variation
  - Distributions
  - Common vs. special cause variation
- Run charts
- Common SPC charts (EXCEL Demos)
  - P-chart, U-chart, $\bar{x}$-chart, s-chart
- QI research methods

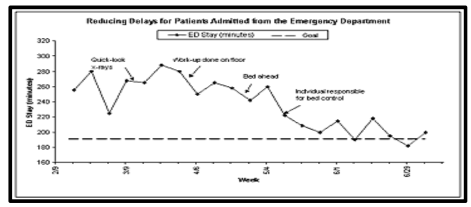
What is Statistical Process Control (SPC)?

- Collection of tools (strategy & methods) designed to help us understand processes that generates products or service
- Many, but not all, of the tools are statistical…



Fishbone Diagrams


Flow Charts



Run Charts

- Studying the underlying behavior of a process helps us
  - Understand why it behaves the way it does
  - Exercise control over the process
  - Assists in redesign and improvement

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Origin of Statistical Process Control (SPC)

History in industry

- Walter Shewhart developed first SPC charts in late 20's to improve quality of telephone produced by Bell Laboratories
- Post WWII Japanese policy explicitly chose quality as its national goal for economic survival
  - Desire for industry to manufacture quality products consistently & efficiently
  - US experts (Edward Deming – statistical skills & Joseph Juran – management skills) sent to help change attitudes about quality management
- Following Japan's success, US started paying attention to quality in industry

History in industry

- Same techniques had been taught in US for years, but with limited success in the US due to…
  - Quality was confined to a "quality department"
  - Management did not accept responsibility for quality
  - Quality was not a continuous process
  - Statistical methods were considered too technical

Still potential barriers to QI in hospitals?

- In the 70's, US started sending people to Japan to learn methods

History of SPC in Healthcare

SPC in healthcare

- Growing applications in healthcare since 90's
- Increasing focus by national organizations
  - IHI emphasis on viewing & analyzing time-ordered data when measuring for improvement
  - The JC began using SPC in accreditation in 1998
- Influence of healthcare leadership from non-healthcare backgrounds
- Growing pressure to deliver value-based care

Challenges for SPC in healthcare

- Can practices developed for producing widgets also apply to healthcare? Yes, but…
  - Deciding on what to measure or count can be challenging in healthcare
  - Use of SPC punitively in scorecards rather than for improvement

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Review of Basic Statistics I

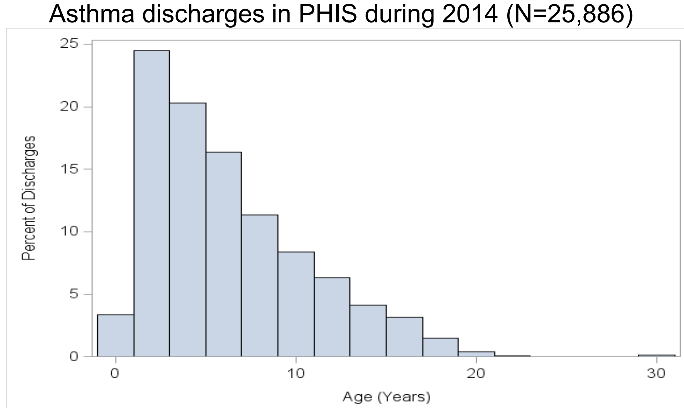
Measures of central tendency and variation:

The foundation for QI Methods

Measures of location

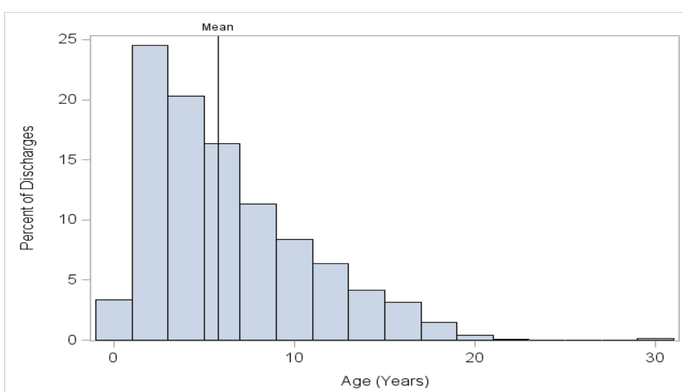
- Tries to measure the ‘center’ or ‘bump’ in histogram
- Common measures
  - Mean
  - Median
  - Mode

Asthma discharges in PHIS during 2014 (N=25,886)



The mean ($\bar{x}$)

- Add all of your measurements together, and divide by the number of measurements.

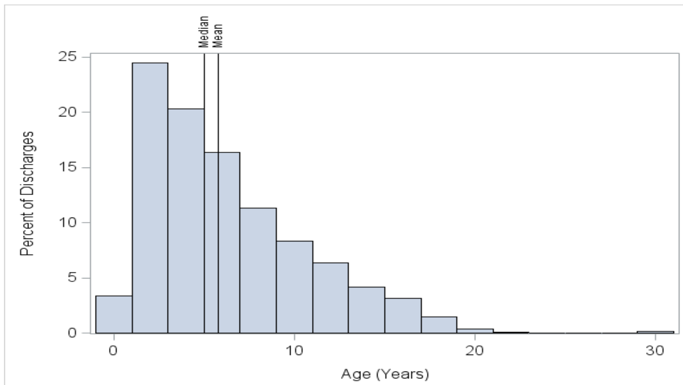


$\bar{x}$ = 5.8

- Sensitive to extreme values or non-normal distributions

The median (P50 – the 50th percentile)

- Sort the data in ascending order. If sample is odd, the median is the middle. If even, the median is the average of two middle values.

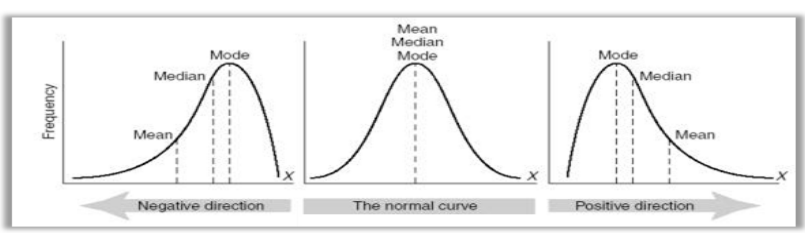


$\bar{x}$ = 5.8
P50 = 5.0

- Less sensitive to extreme values. Better for small sample sizes

Characteristics of the mean and median

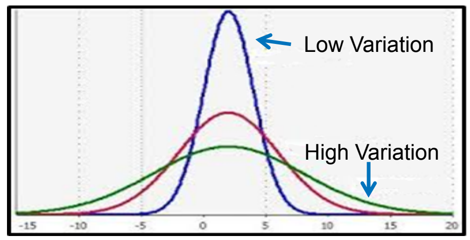
- If the mean and median are close, then the "bump" is symmetric.
- If the mean is larger than the median, then the "bump" is skewed to the right
- If the mean is smaller than the median, then the "bump" is skewed to the left



Measures of spread (or variation)

- Measure the 'width' of the 'bump' in the histogram.
- If two distributions have the same mean, then the larger the value of spread is, the flatter the "bump"

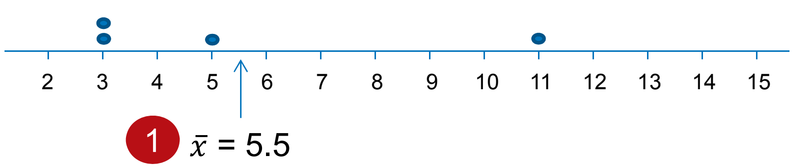
- Common measures
  - Range
  - Variance
  - Standard Deviation
  - Interquartile Range (P75-P25)



Variance (s^2) and standard deviation (s)

- The variance is the average of the squared distance that each value is away from the mean

$$\frac{1}{n-1}\sum_{i=1}^{n}\left(x_i - \bar{x}\right)^2$$



x	$x-\bar{x}$ (2)	$(x-\bar{x})^2$ (3)
3	-2.5	6.25
3	-2.5	6.25
5	-0.5	0.25
11	5.5	30.25
	Total:	43 (4)

(5) $s^2 = 43/4 = 10.8$

- The standard deviation is just the square root of the variance

s = 3.3

SAS output

The SAS System

The UNIVARIATE Procedure
Variable: age (age)

Moments			
N	25886	Sum Weights	25886
Mean	5.77037781	Sum Observations	149372
Std Deviation	4.44155977	Variance	19.7274532
Skewness	1.07924568	Kurtosis	1.28550682
Uncorrected SS	1372578	Corrected SS	510645.126
Coeff Variation	76.9717324	Std Error Mean	0.02760597

Basic Statistical Measures			
Location		Variability	
Mean	5.770378	Std Deviation	4.44156
Median	5.000000	Variance	19.72745
Mode	1.000000	Range	30.00000
		Interquartile Range	6.00000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	209.0264	Pr > |t|	<.0001
Sign	M	12507.5	Pr >= |M|	<.0001
Signed Rank	S	1.5644E8	Pr >= |S|	<.0001

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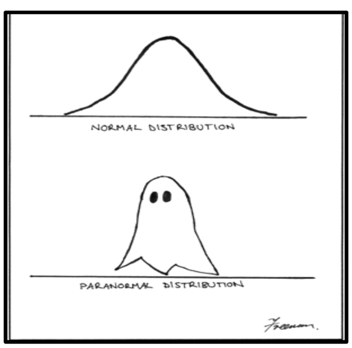
Review of Basic Statistics II

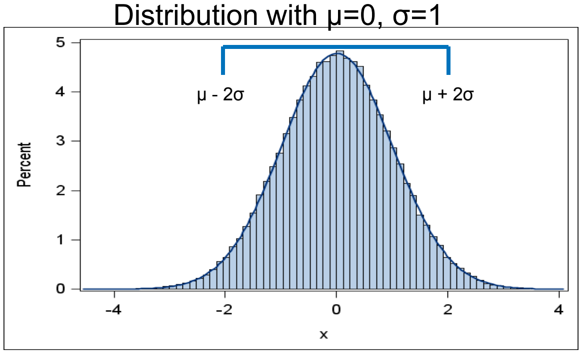
Distributions



Normal distributions

- Data that follow a normal distribution will have a symmetric histogram around the mean
- 2 parameters (mean μ, standard deviation σ) uniquely describe a normal distribution

Distribution with μ=0, σ=1

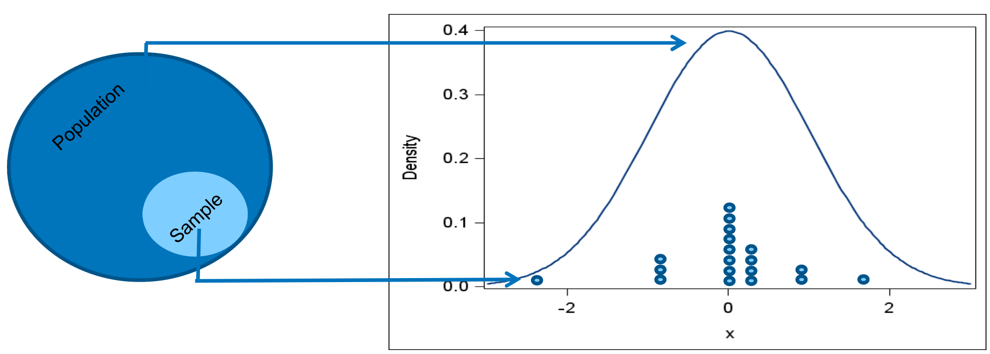


Approximately…
68.2% of the data will be within 1σ of μ
95.4% will be within 2σ of μ
99.8% will be within 3σ of μ

Caution: Most healthcare data (e.g. LOS, cost) are not normal.

Normal distributions

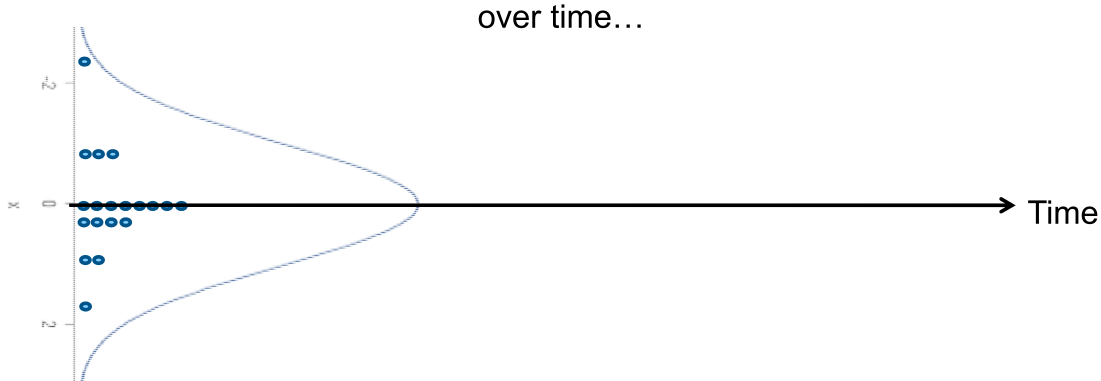
- When selecting a sample from a population, it is very unlikely that data will come from the tails



4.6% chance beyond 2σ, 0.2% chance beyond 3 σ

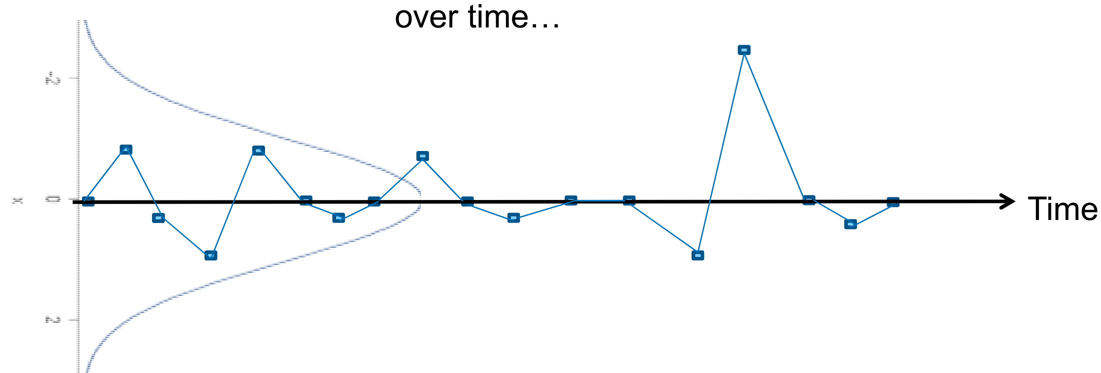
Normal distributions

Turn the distribution on its side and suppose the data is being collected over time…



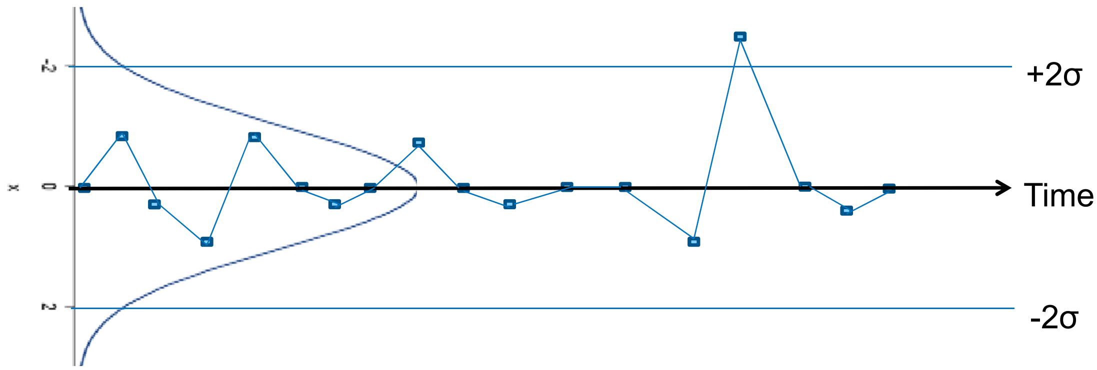
Normal distributions

Turn the distribution on its side and suppose the data is being collected over time…

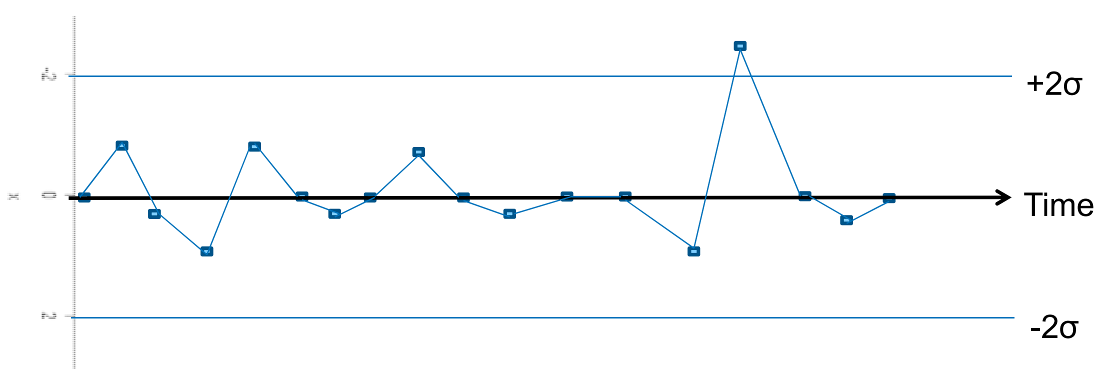


Normal distributions

Extend the 2σ bands…



Normal distributions

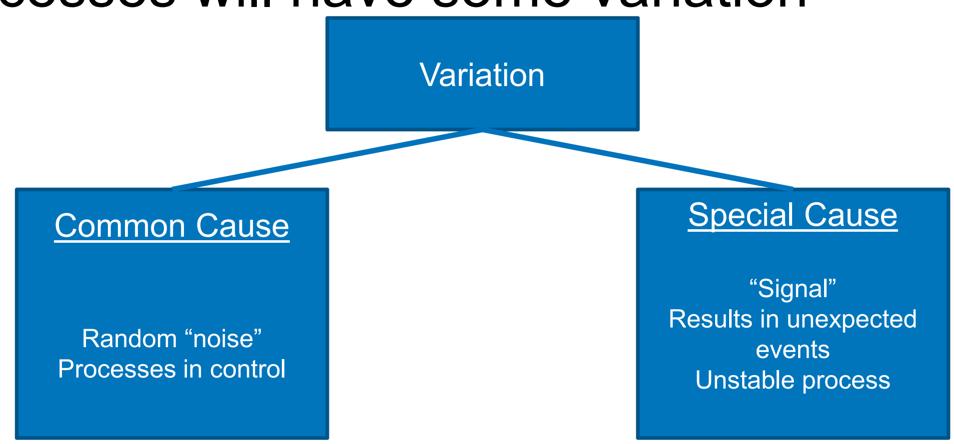


You have just created a control chart!

Review of Basic Statistics III

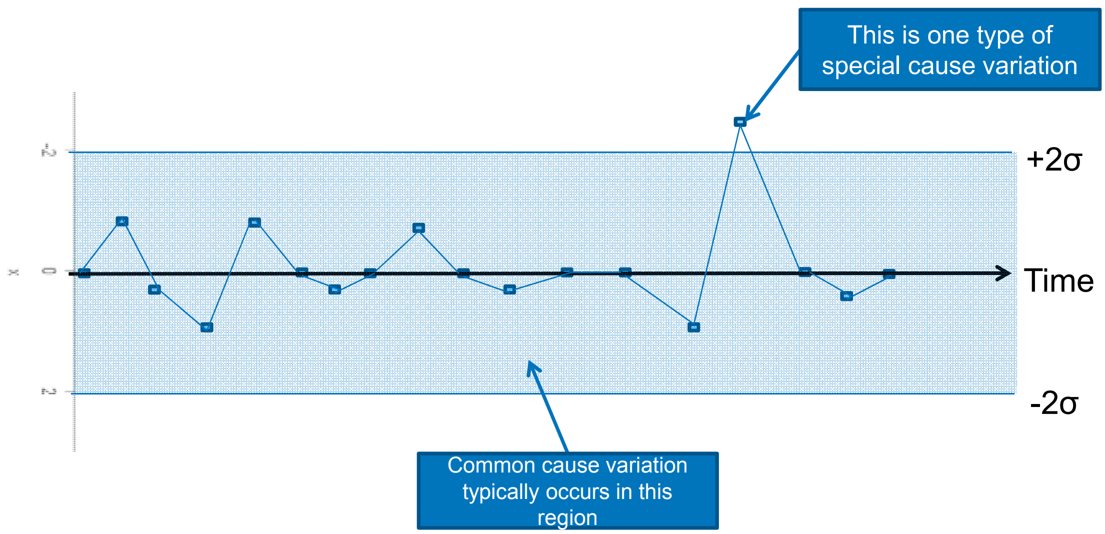
Common vs. special cause variation

When monitoring a process over time, all processes will have some variation



SPC attempts to separate out these types of variation

Special and common cause variation



Special and common cause variation

- <u>Western Electric Rules</u> are one common method for identifying special cause variation
  - Rule 1. Any point beyond 3σ
  - Rule 2: Two out of three consecutive points fall outside 2σ
  - Rule 3: Four out of five consecutive points fall outside 1σ
  - Rule 4. Nine consecutive points on the same side of the center line
- There are other sets of rules available

Run Charts

Run charts

- Charting time ordered data to detect…
  a) Long-term trends
  b) Unusual patterns
- Construction:
  - X-axis: time
  - Y-axis: measurement
  - Include baseline median as a reference line

Probability based rules

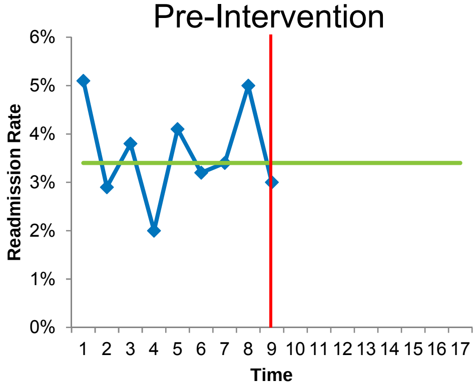
These scenarios are very unlikely to occur randomly…

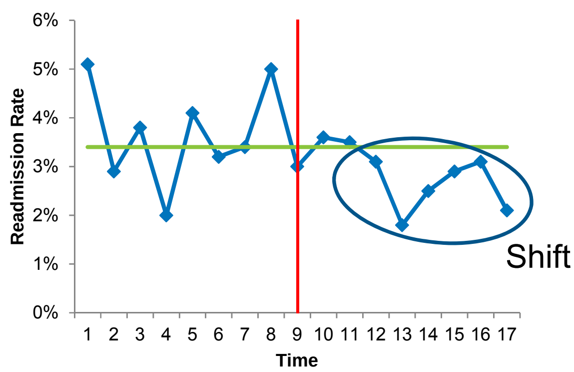
- Shift: 6+ consecutive points on one side of the median

Prob = 1.6%

- Trend: 5+ consecutive points increasing or decreasing

Example – 15 day readmission for asthma





Why use a run chart?

- It's easy!
- Useful first step in analyses
- Not enough data points to construct a control chart

Why not use a run chart?

- Over reacting
- Detection of outliers is difficult & subjective

Common SPC Charts

Generic process to develop SPC charts

1. Determine what type of measure you have
2. Determine the appropriate control chart to create
3. Calculate the centerline for the data (our best guess at "normal")
4. Calculate the bounds for “normal” behavior (a.k.a. control limits)
5. Decide what behavior you are going to consider abnormal using some rules

Common SPC Charts

Type of Measure	Example	Type of Control Chart
Proportional	Proportion of Intensive Care Unit (ICU) patients that are intubated	p-chart
Ratio	Number of bloodstream infections per 1000 line days	u-chart
Continuous	Average length of stay in the ED	x-bar, s-chart
Days Between (Rare Outcomes)	Never events	g-chart

Common SPC Charts

P Chart & U Charts

Working example – Readmissions

Our hospital is interested in tracking the proportion of patients readmitted within 30 days

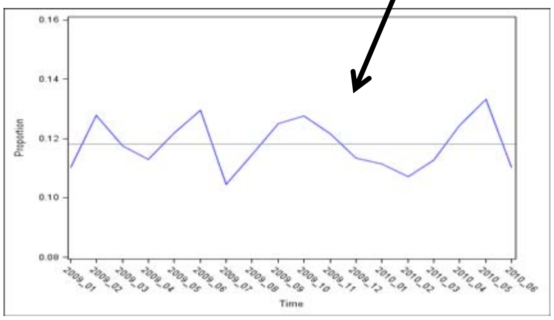
Yr_Month	Num	Den	Proportion
2009_01	152	1381	0.110
2009_02	162	1266	0.128
2009_03	159	1352	0.118
2009_04	135	1194	0.113
2009_05	141	1158	0.122
2009_06	163	1258	0.130
2009_07	136	1301	0.105
2009_08	136	1188	0.114
2009_09	159	1270	0.125
2009_10	176	1379	0.127
2009_11	149	1224	0.128
2009_12	143	1260	0.113
2010_01	147	1320	0.111
2010_02	146	1363	0.107
2010_03	156	1383	0.113
2010_04	151	1213	0.124
2010_05	157	1178	0.133
2010_06	134	1216	0.110
Sum	2702	22904	

1. Determine what type of measure you have – proportion
2. Determine the appropriate control chart to create – p chart
3. Calculate the centerline for the data

$$\bar{p} = \frac{152 + 162 + 159 + \cdots + 134}{1381 + 1266 + 1352 + \cdots + 1216} = \frac{2702}{22904} = 0.1180$$

Working example – Readmissions

Is the variation just random?



$$UCL = \bar{p} + 3 * \sqrt{\frac{\bar{p} * (1 - \bar{p})}{month's\ denominator}}$$

$$LCL = \bar{p} - 3 * \sqrt{\frac{\bar{p} * (1 - \bar{p})}{month's\ denominator}}$$

3σ limits

4. Calculate the bounds for "normal" behavior (a.k.a. control limits)

- Change month-to-month based on denominator size

Smaller Denominator ► Wider Limits

- Width also based on our tolerance for false positives...

2σ ► More outliers, ▲ likelihood of false +

3σ ► Fewer outliers, ▼ likelihood of false +

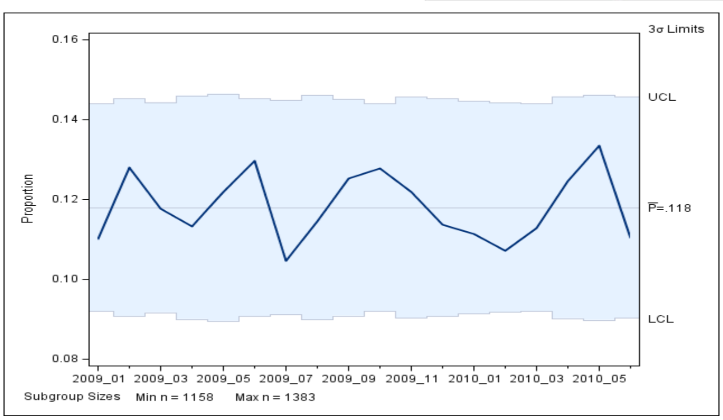
Working example – Readmissions

Example calculation of control limit

Yr_Month	Num	Den	Proportion
2009_01	152	1381	0.110

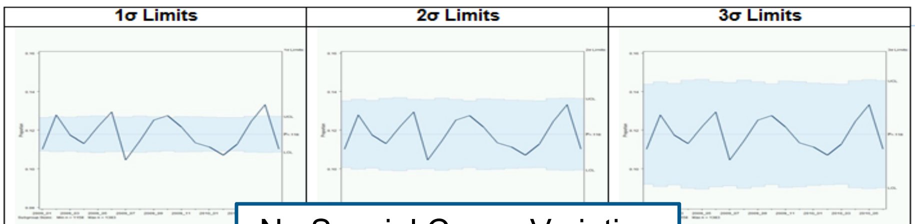
$$UCL = 0.1180 + 3 * \sqrt{\frac{0.1180 * (1 - 0.1180)}{1381}} = 0.1475$$

$$LCL = 0.1180 - 3 * \sqrt{\frac{0.1180 * (1 - 0.1180)}{1381}} = 0.0920$$



Identifying "special cause" variation

5. Decide what behavior you are going to consider abnormal using some rules
   - Western Electric Rules
     - Rule 1. Any point beyond 3σ
     - Rule 2: Two out of three consecutive points fall outside of 2σ
     - Rule 3: Four out of five consecutive points fall outside of 1σ
     - Rule 4. Nine consecutive points on the same side of the center line



No Special Cause Variation

EXCEL Demo

U Charts – Ratio measures

- Construction is nearly identical to P Charts
  - The center line $(\bar{u})$ is calculated in the same way
  - The control limits are similar

$$UCL = \bar{u} + 3 * \sqrt{\frac{\bar{u}}{month's\ denominator}}$$

$$LCL = \bar{u} - 3 * \sqrt{\frac{\bar{u}}{month's\ denominator}}$$

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Common SPC charts

$\bar{x}$-chart ("x bar" chart) for average

s-chart for standard deviation

Working example – Length of stay

Our hospital is interested in tracking the average postoperative length of stay in the NICU for babies who have undergone a Patent Ductus Arteriosus (PDA) ligation

Yr_Month	Number of cases	Mean LOS (days)	St.dev. LOS (days)
2009_Jan	6	15.3	1.2
2009_Feb	5	14.2	1.4
2009_Mar	6	14.1	2.2
2009_Apr	6	16.0	1.2
2009_May	7	13.8	1.2
2009_Jun	5	14.3	2.4
2009_Jul	6	15.2	1.2
2009_Aug	6	15.2	2.4
2009_Sep	5	14.6	2.4
2009_Oct	6	15.5	1.2
2009_Nov	6	14.9	1.4
2009_Dec	7	16.2	2.2
2010_Jan	6	14.8	1.5
2010_Feb	6	15.4	3.4

1. Determine what type of measure you have – continuous
2. Determine the appropriate control chart to create – x-bar, s-chart
3. Calculate the centerline for the data (our best guess at "normal")

$$\bar{s} = \frac{1.2+1.4+\cdots+1.5+3.4}{14} = 1.8$$

$$\bar{x} = \frac{15.3+14.2+\cdots+14.8+15.4}{14} = 15$$

Working example – Length of stay

4. Calculate the bounds for "normal" behavior (a.k.a. control limits)

s-chart

LCL = $B_3 \bar{s}$
UCL = $B_4 \bar{s}$

$\bar{x}$-chart

LCL = $\bar{x} - A_3 \bar{s}$
UCL = $\bar{x} + A_3 \bar{s}$

Anti-biasing constants based on sample size

Anti-biasing constants

Subgroup Sample Size n	Factors for Control Limits: $\bar{X}$ (Average) Chart, Using $\bar{R}$ A_2	$\bar{X}$ (Average) Chart, Using $\bar{S}$ A_3	$\tilde{X}$ (Median) Chart, Using $\bar{R}$ A_6	R (Range) Chart, Using $\bar{R}$ D_3	R (Range) Chart, Using $\bar{R}$ D_4	S (Std. Dev.) Chart, Using $\bar{S}$ B_3	S (Std. Dev.) Chart, Using $\bar{S}$ B_4	Factors for Estimating Process σ_x: Using $\bar{R}$ d_2	Using $\bar{S}$ c_4
2	1.880	2.659		0	3.267	0	3.267	1.128	.7979
3	1.023	1.954	1.187	0	2.575	0	2.568	1.693	.8862
4	.729	1.628		0	2.282	0	2.266	2.059	.9213
5	.577	1.427	.691	0	2.114	0	2.089	2.326	.9400
6	.483	1.287		0	2.004	.030	1.970	2.534	.9515
7	.419	1.182	.509	.076	1.924	.118	1.882	2.704	.9594
8	.373	1.099		.136	1.864	.185	1.815	2.847	.9650
9	.337	1.032	.412	.184	1.816	.239	1.761	2.970	.9693
10	.308	.975		.223	1.777	.284	1.716	3.078	.9727
11	.285	.927	.350	.256	1.744	.321	1.679	3.173	.9754
12	.266	.886		.283	1.717	.354	1.646	3.258	.9776
13	.249	.850		.307	1.693	.382	1.618	3.336	.9794
14	.235	.817		.328	1.672	.406	1.594	3.407	.9810
15	.223	.789		.347	1.653	.428	1.572	3.472	.9823
16	.212	.763		.363	1.637	.448	1.552	3.532	.9835
17	.203	.739		.378	1.622	.466	1.534	3.588	.9845
18	.194	.718		.391	1.609	.482	1.518	3.640	.9854
19	.187	.698		.404	1.596	.497	1.503	3.689	.9862
20	.180	.680		.415	1.585	.510	1.490	3.735	.9869
Formulas in Which Factors Are Used									
UCL:	$\bar{\bar{X}}+A_2\bar{R}$	$\bar{\bar{X}}+A_3\bar{S}$	$\bar{\tilde{X}}+A_6\bar{R}$	$D_4\bar{R}$		$B_4\bar{S}$		$\frac{\bar{R}}{d_2}$	$\frac{\bar{S}}{c_4}$
LCL:	$\bar{\bar{X}}-A_2\bar{R}$	$\bar{\bar{X}}-A_3\bar{S}$	$\bar{\tilde{X}}-A_6\bar{R}$	$D_3\bar{R}$		$B_3\bar{S}$			

All values, except A_6, from ASTM Manual #7, *Manual on Presentation of Data and Control Chart Analysis: 6th Edition*, Table 49, p. 91, 1992, by kind permission of the American Society for Testing and Materials, Philadelphia. Factor A_6 from L. S. Nelson, "Control Charts for Medians," *Journal of Quality Technology*, October 1982, p. 226.

*Pitt, H. (1994). *SPC For the Rest of Us. A Personal Path to Statistical Process Control.* Addison-Wesley Publishing Company, Inc.

Working example – Length of stay

Yr_Month	Number of cases	Mean LOS (days)	St.dev. LOS (days)
2009_Jan	6	15.3	1.2

Use to look up anti-biasing constants

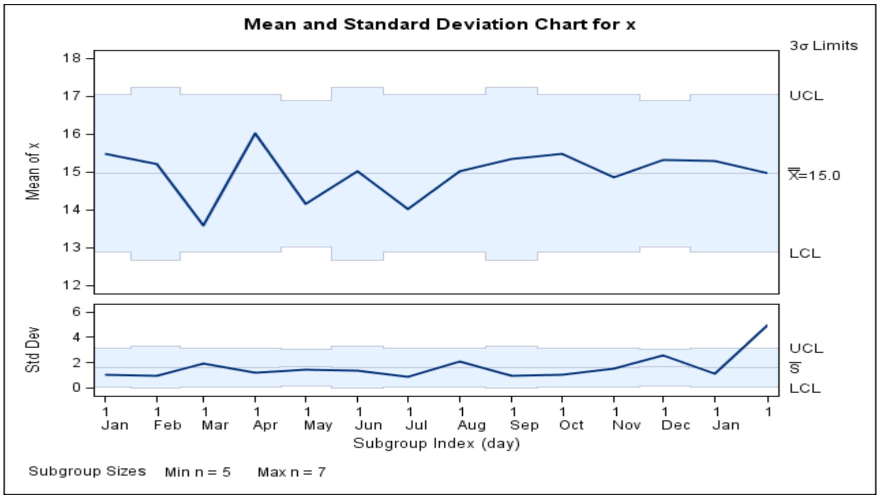
s-chart

LCL = $B_3\,\bar{s}$ = 0.03 * 1.8 = 0.05
UCL = $B_4\,\bar{s}$ = 1.97 * 1.8 = 3.5

$\bar{x}$-chart

LCL = $\bar{x}$ - $A_3\,\bar{s}$ = 15 - 1.287*1.8 = 12.7
UCL = $\bar{x}$ + $A_3\,\bar{s}$= 15 - 1.287*1.8 = 17.3

Working example – Length of stay



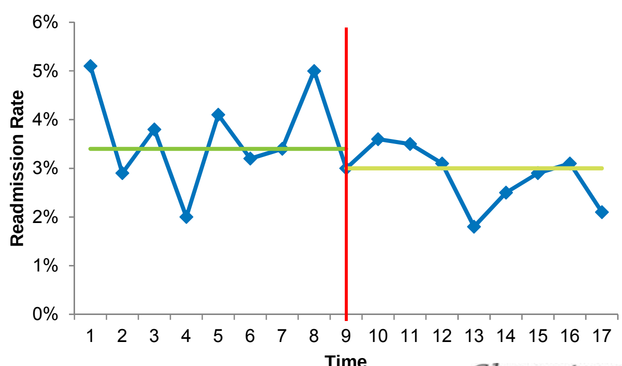
EXCEL Demo

Things to keep in mind

- It is assumed that the process is in control when you construct your control chart
- The measurements between periods should be independent. If you have seasonality in your data, standard charts won't work for you
- Rule of thumb: You need a minimum of 10 data points to construct a control chart

Resetting the middle line

- Consider resetting the middle line if…
  – A change in the process has been detected analytically and verified that the process has changed
  – An intervention has occurred

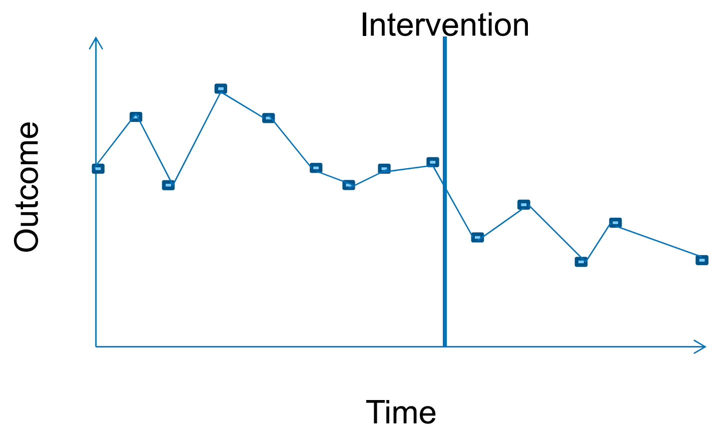


QI Research Methods

Champions for Children's Health

QI research

Establish a relationship between process changes and outcomes



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Study designs

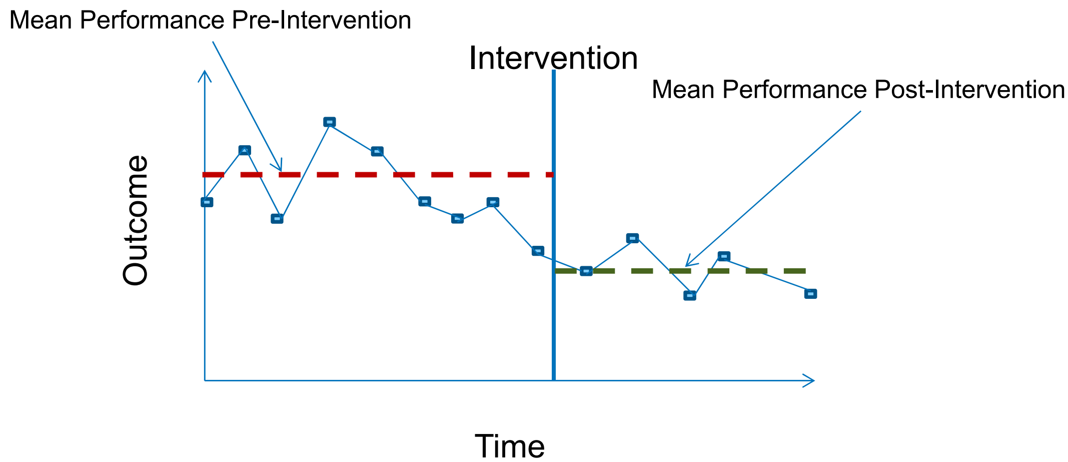
Pre-post

- Aggregates pre-intervention data into a single data point and compares it to aggregated post-intervention data

Interrupted time-series (ITS)

- Determines if a level-shift occurred in the series at the time of the intervention
- Estimates the change in the trend that occurred at the time of the intervention

Pre-post design



We ignored that the performance was improving pre-intervention!
Can we really attribute the change to the intervention?

Pre-post example

An Intervention to Decrease Narcotic-Related Adverse Drug Events in Children's Hospitals
Paul J. Sharek, Richard E. McClead, Jr, Carol Taketomo, Joseph W. Luria, Glenn S. Takata, Beverly Walti, Marla Tanski, Carla Nelson, Tina R. Logsdon, Cary Thurm and Frank Federico
Pediatrics 2008;122;e861
DOI: 10.1542/peds.2008-1011

Narcotic-related ADE rates were compared between the baseline (Jan 04-Mar 05) and post implementation periods (Jan 06-Mar 06).

TABLE 4 Percentage Reduction in Constipation Rates Collaborative-Wide From Baseline

Quarter	% Reduction in Constipation ($n = 13$)			
	Median	25th Percentile	75th Percentile	*P*
1[a]	29.0	−7.8	66.8	.14648
2	38.3	−5.1	61.6	.15137
3	45.6	0.9	72.8	.09229
4	68.9	60.5	94.2	.00049

[a] April 1, 2005, through June 30, 2005.

Interrupted time-series (ITS)

ITS will take into account the pre-intervention trend

$$Y_t = \beta_0 + \beta_1 time_t + \beta_2 intervention_t + \beta_3 time\ after\ intervention_t + e_t$$

Y_t is the outcome for month t

β_0 is the baseline outcome at t=0

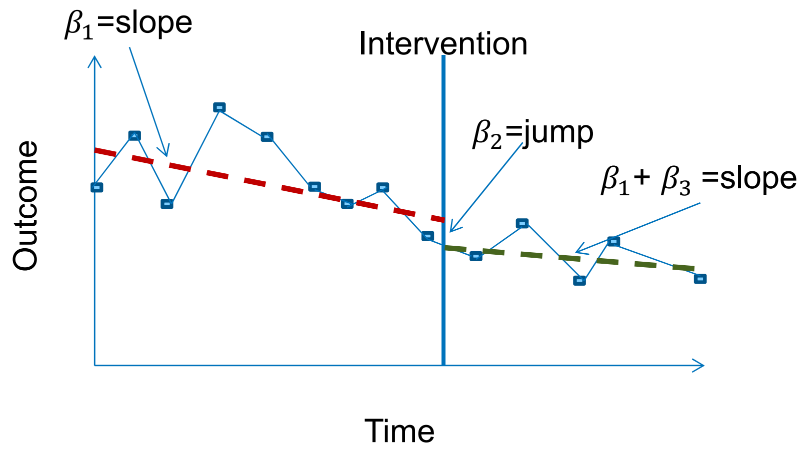
β_1 is the slope (change) of the line pre-intervention

β_2 is the level change in the outcome at the intervention

β_3 is the change in the slope pre- to post-intervention

β_1 + β_3 is the post-intervention slope

Interrupted time-series (ITS)



Example–Impact of National T&A Guidelines

Association of National Guidelines with Tonsillectomy Perioperative Care and Outcomes

Sanjay Mahant, Matt Hall, Stacey L. Ishman, Rustin Morse, Vineeta Mittal, Grant M. Mussman, Jessica Gold, Amanda Montalbano, Rajendu Srivastava, Karen M. Wilson, Samir S. Shah

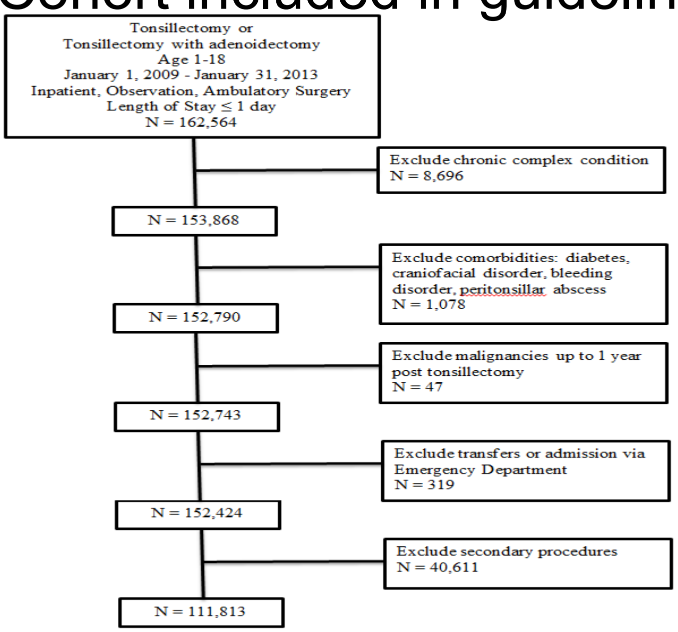
Pediatrics published online: June 22, 2015

- 2011 American Academy of Otolaryngology Head and Neck Surgery guidelines
  - Evidence-based recommendations for the perioperative use of dexamethasone, no routine use of antibiotics, discharge education of families and for monitoring of bleeding complication rates
- The impact of the guidelines on tonsillectomy processes and outcomes are unknown

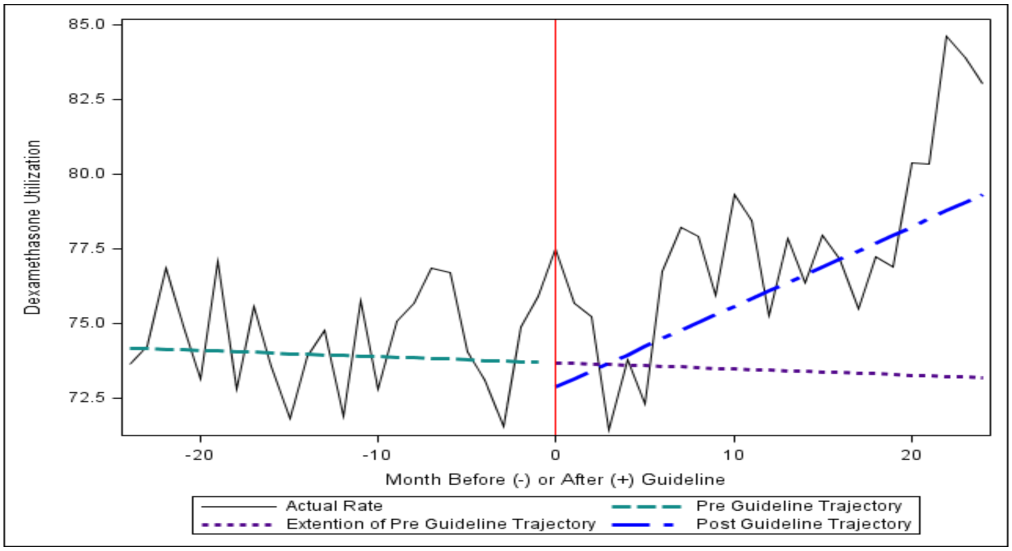
Methods

- PHIS data from 29 hospitals with ambulatory surgery between 2009-2013
- Inclusion
  – Age 1-18
  – Procedure code of tonsillectomy (28.2) or tonsillectomy and adenoidectomy (28.3)
- Exclusions
  – diagnosis of peritonsillar abscess
  – chronic complex conditions
  – malignancy diagnosis
  – non-elective
  – children who had concomitant procedures (e.g. tympanostomy tubes)

Cohort included in guideline



Use of dexamethasone increased 5.9%



79.0% with guideline

73.1% without guideline

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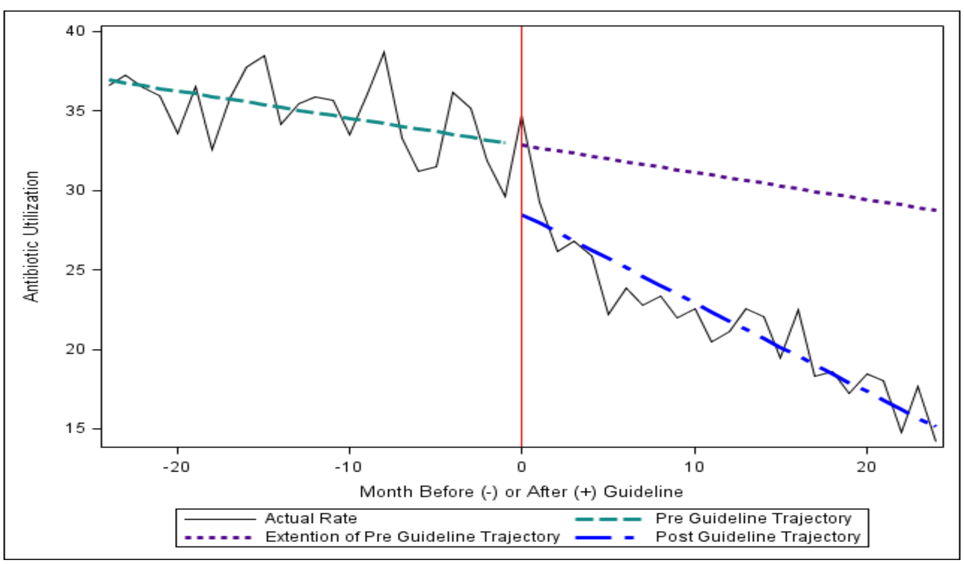
Use of antibiotics decreased 13.7%



28.8% without guideline

15.1% with guideline

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Study designs

ITS is always preferable, but requires longer data collection and more sophisticated methods of analyses

Pre-post designs can be used for internal QI purposes or for pilot studies

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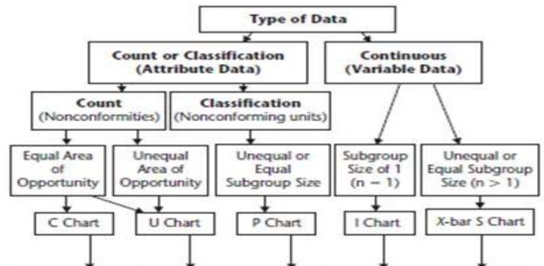
FIGURE 7.1 Expanded Chart Selection Guide to Include Alternative Charts



Alternative Advanced Types of Shewhart or Time Series Charts	C Chart	U Chart	P Chart	I Chart	Xbar S Chart
NP Chart			x		
$\bar{X}$-bar and range Chart					x
Median Chart					x
T chart (time between rare events)	x	x			
G Chart (opportunities between rare events)	x	x	x		
Moving average Chart				x	x
Cumulative sum (CUSUM) Chart	x	x	x	x	x
Exponentially weighted moving average	x	x	x	x	x
Standardized Control Chart	x	x	x	x	x
Multivariate Control Chart				x	x

Note: The "x" in the table indicates that the alternate chart in the table row could be considered for use instead of the basic chart in the table column.