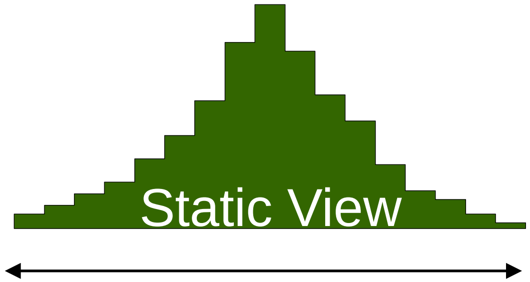
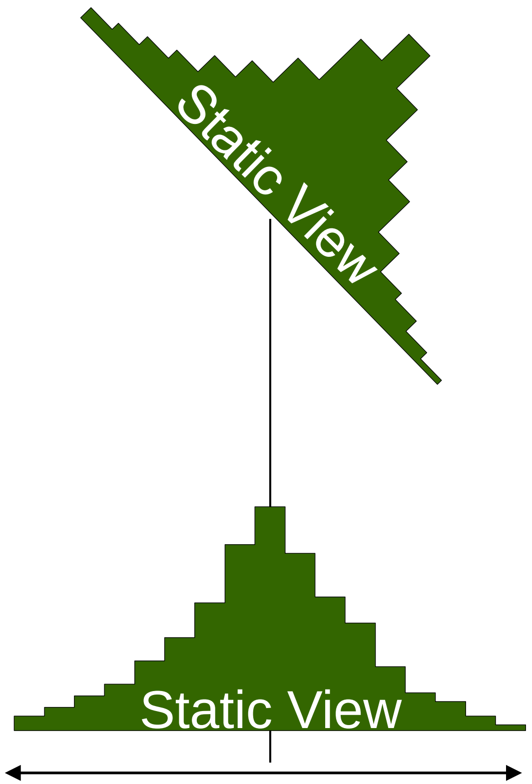
"What is the variation in one system over time?"

Walter A. Shewhart - early 1920's, Bell Laboratories



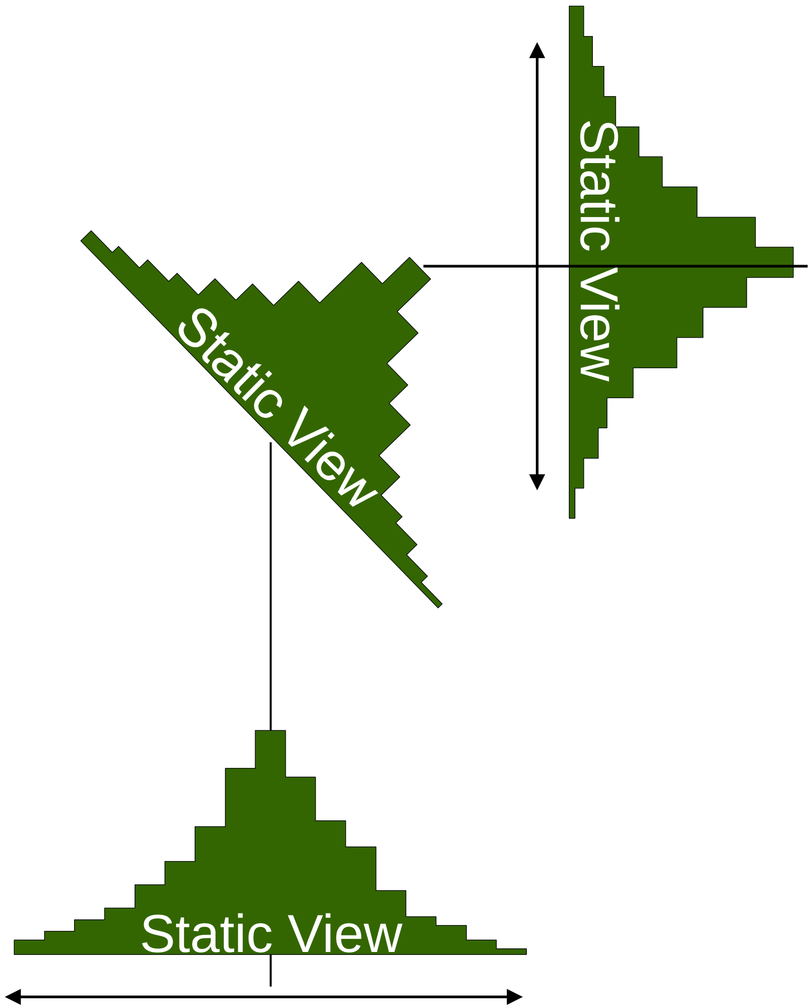
“What is the variation in one system over time?”

Walter A. Shewhart - early 1920’s, Bell Laboratories



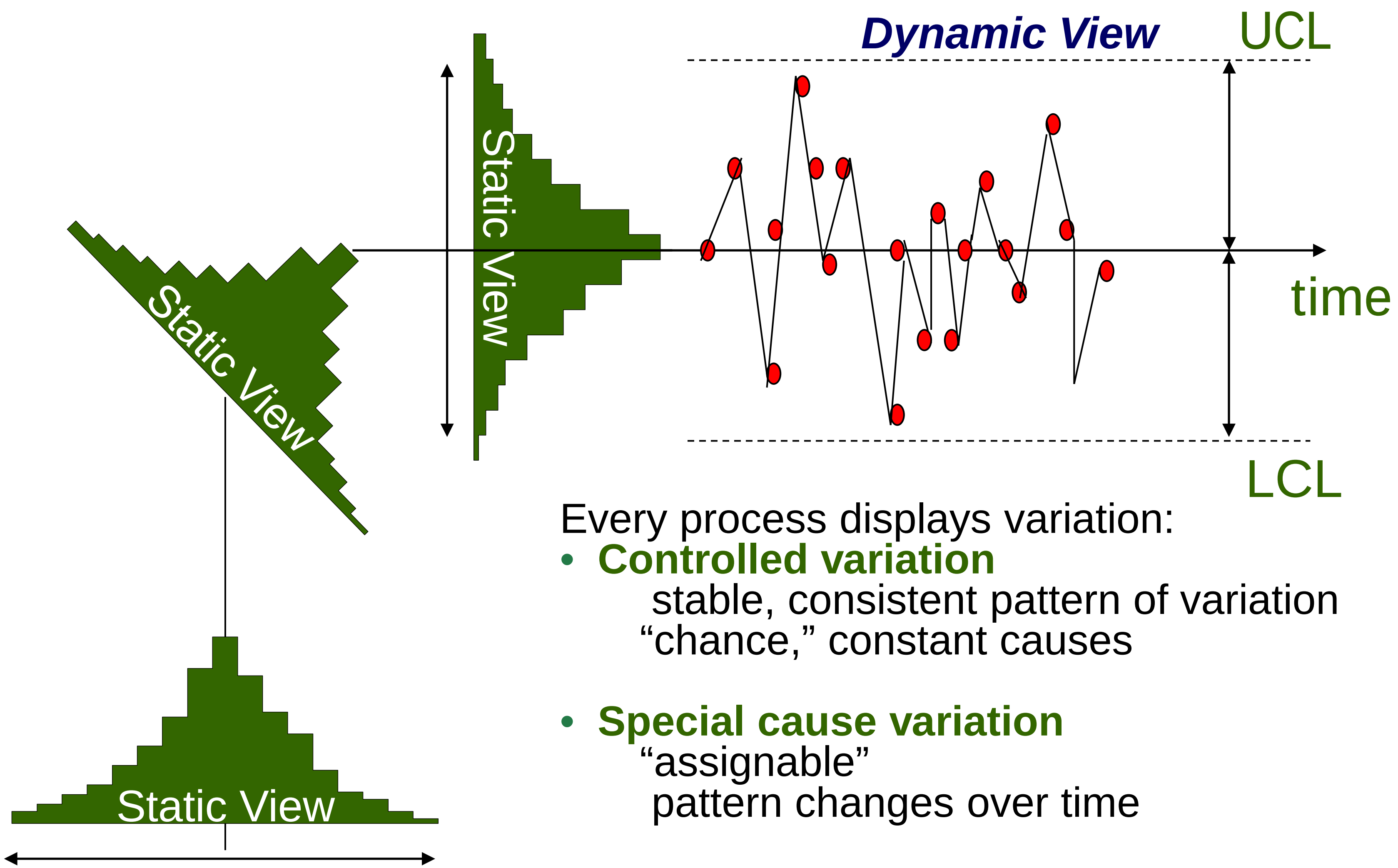
"What is the variation in one system over time?"

Walter A. Shewhart - early 1920's, Bell Laboratories



"What is the variation in one system over time?"

Walter A. Shewhart - early 1920's, Bell Laboratories



Every process displays variation:

- **Controlled variation**
  stable, consistent pattern of variation
  "chance," constant causes

- **Special cause variation**
  "assignable"
  pattern changes over time

Types of Variation

Common Cause Variation

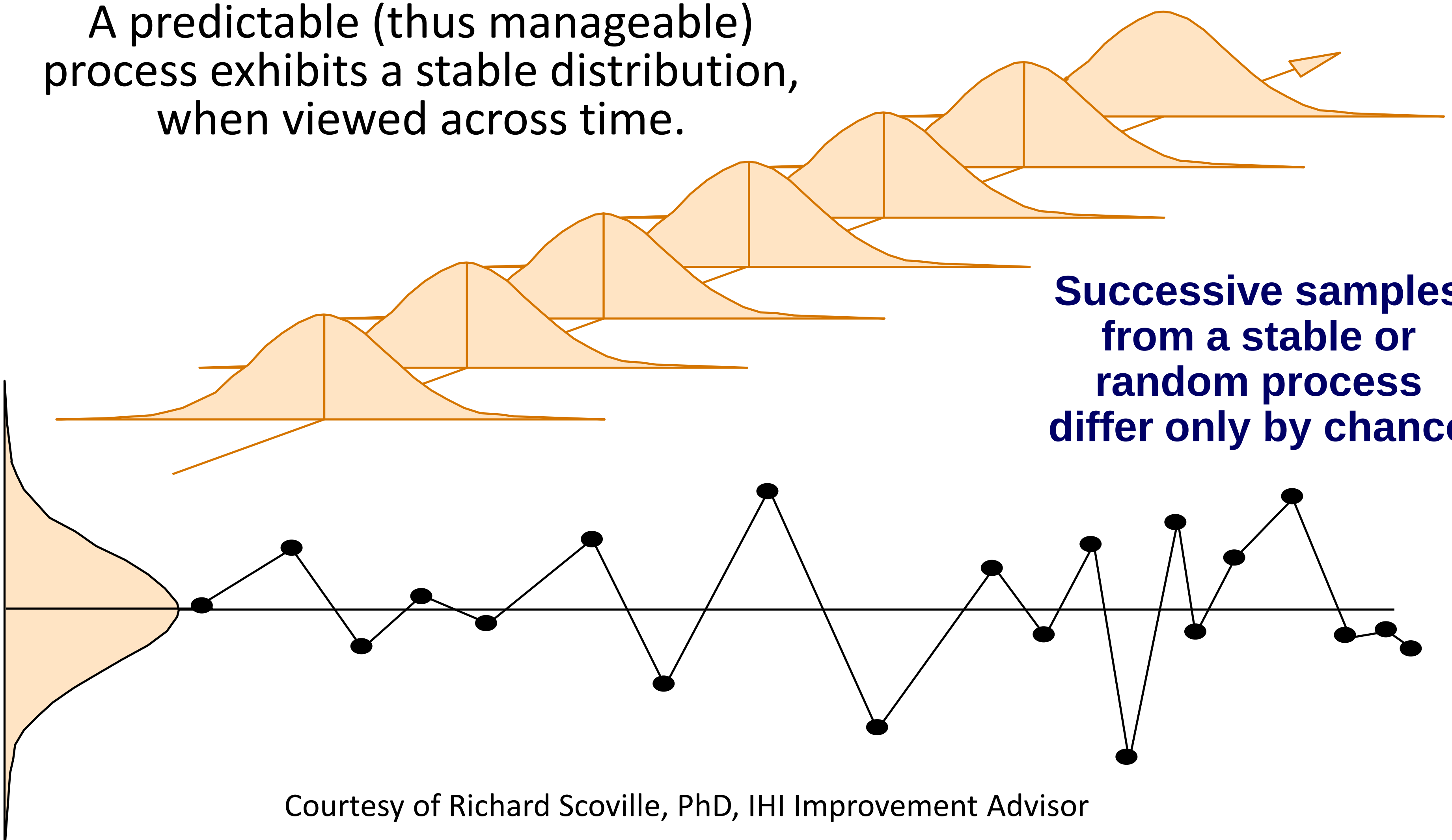
- *Is inherent in the design of the process*
- *Is due to regular, natural or ordinary causes*
- *Affects all the outcomes of a process*
- *Results in a "stable" process that is predictable*
- *Also known as random or unassignable variation*

Special Cause Variation

- *Is due to irregular or unnatural causes that are not inherent in the design of the process*
- *Affect some, but not necessarily all aspects of the process*
- *Results in an "unstable" process that is not predictable*
- *Also known as non-random or assignable variation*

A Stable Process

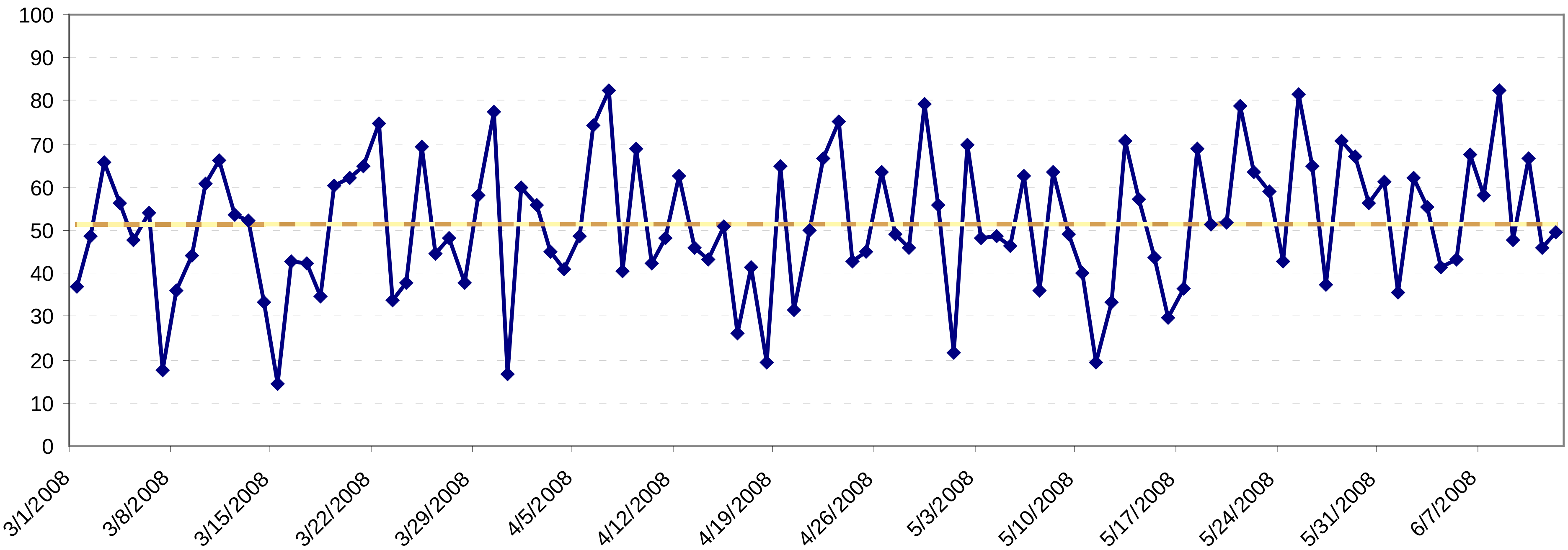
A predictable (thus manageable) process exhibits a stable distribution, when viewed across time.



Successive samples from a stable or random process differ only by chance

Courtesy of Richard Scoville, PhD, IHI Improvement Advisor

Common Cause Variation

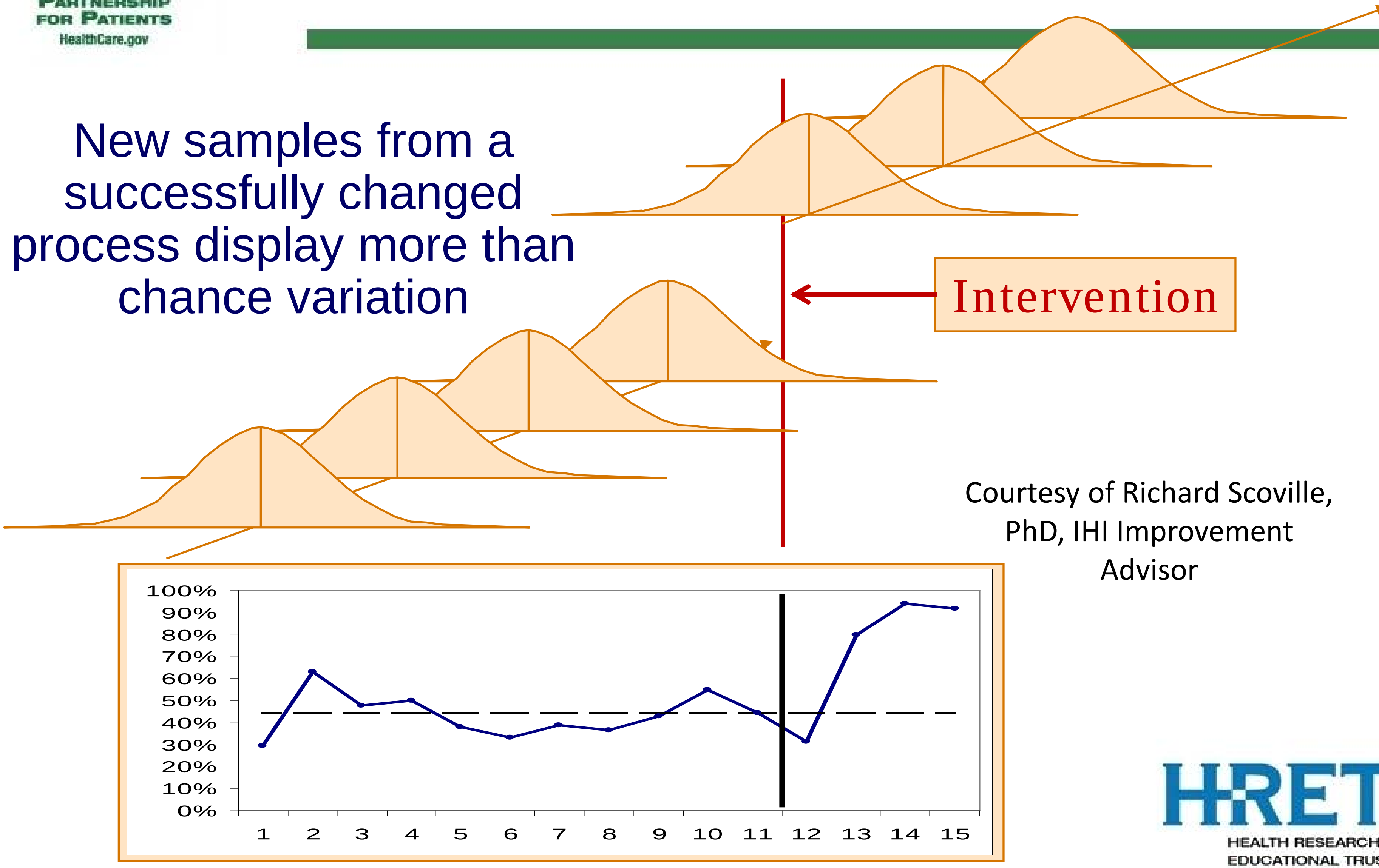


- Points equally likely above or below center line
- There will be a high data point and a low, but this is expected
- No trends or shifts or other patterns

Courtesy of Richard Scoville, PhD, IHI Improvement Advisor

A Successful Change is a Special Cause

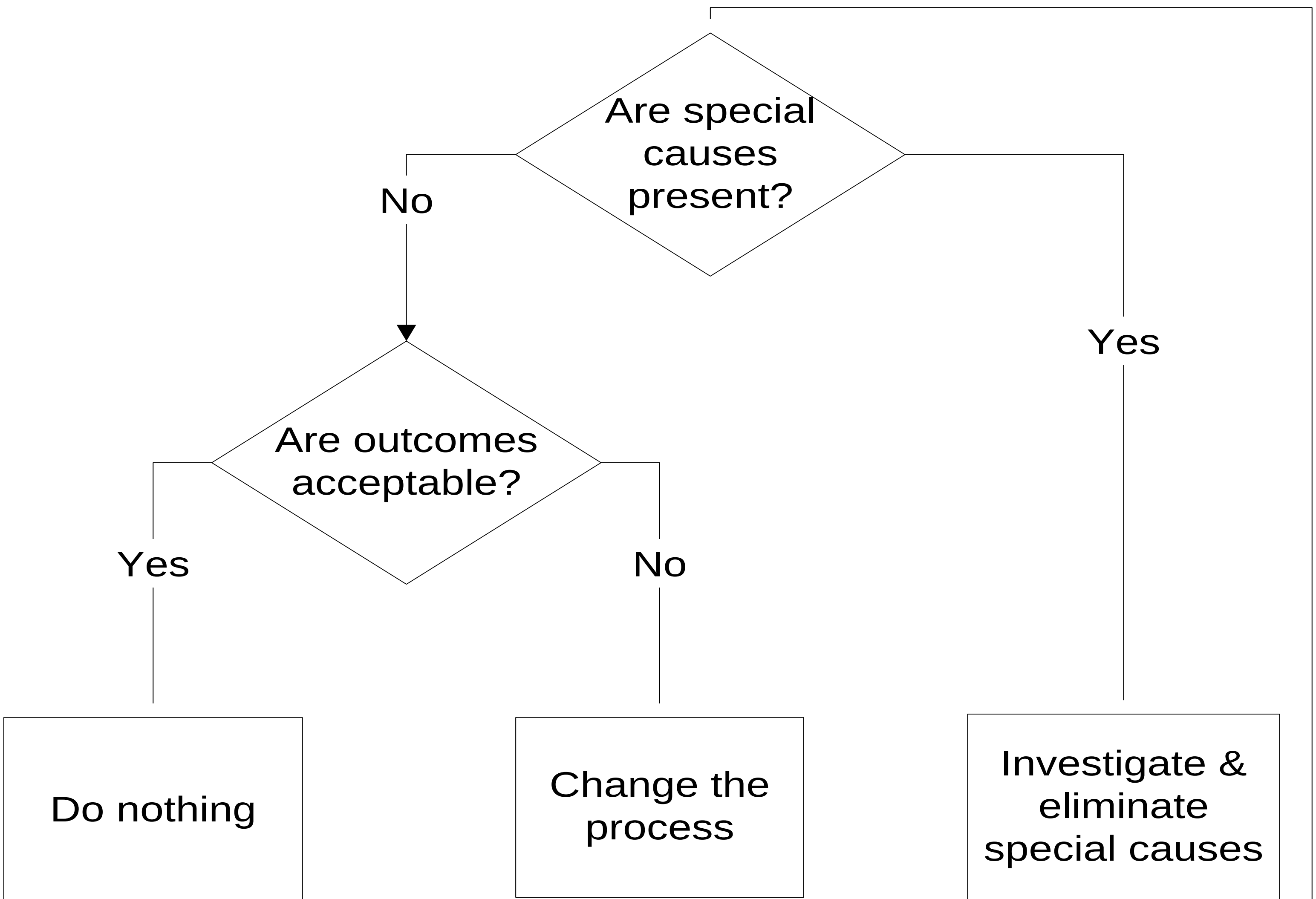
New samples from a successfully changed process display more than chance variation



Courtesy of Richard Scoville, PhD, IHI Improvement Advisor

U.S. Department of Health & Human Services
Partnership for Patients
HealthCare.gov
HRET
Health Research & Educational Trust
In Partnership with AHA

Decision Tree for Managing with Data



© Richard Scoville & IHI

Attributes of a Leader Who Understands Variation

Leaders understand the different ways that variation is viewed.

They explain changes in terms of common causes and special causes.

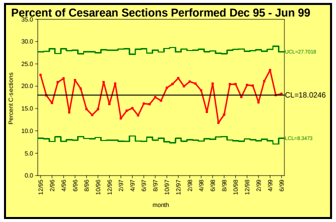
They use graphical methods to learn from data and expect others to consider variation in their decisions and actions.

They understand the concept of stable and unstable processes and the potential losses due to tampering.

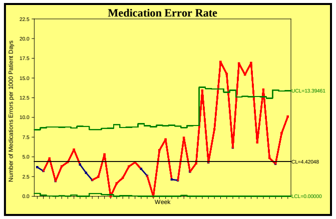
Capability of a process or system is understood before changes are attempted.

Exercise
Common and Special Causes of Variation

- Select several measures your organization is tracking for the HEN Collaborative.



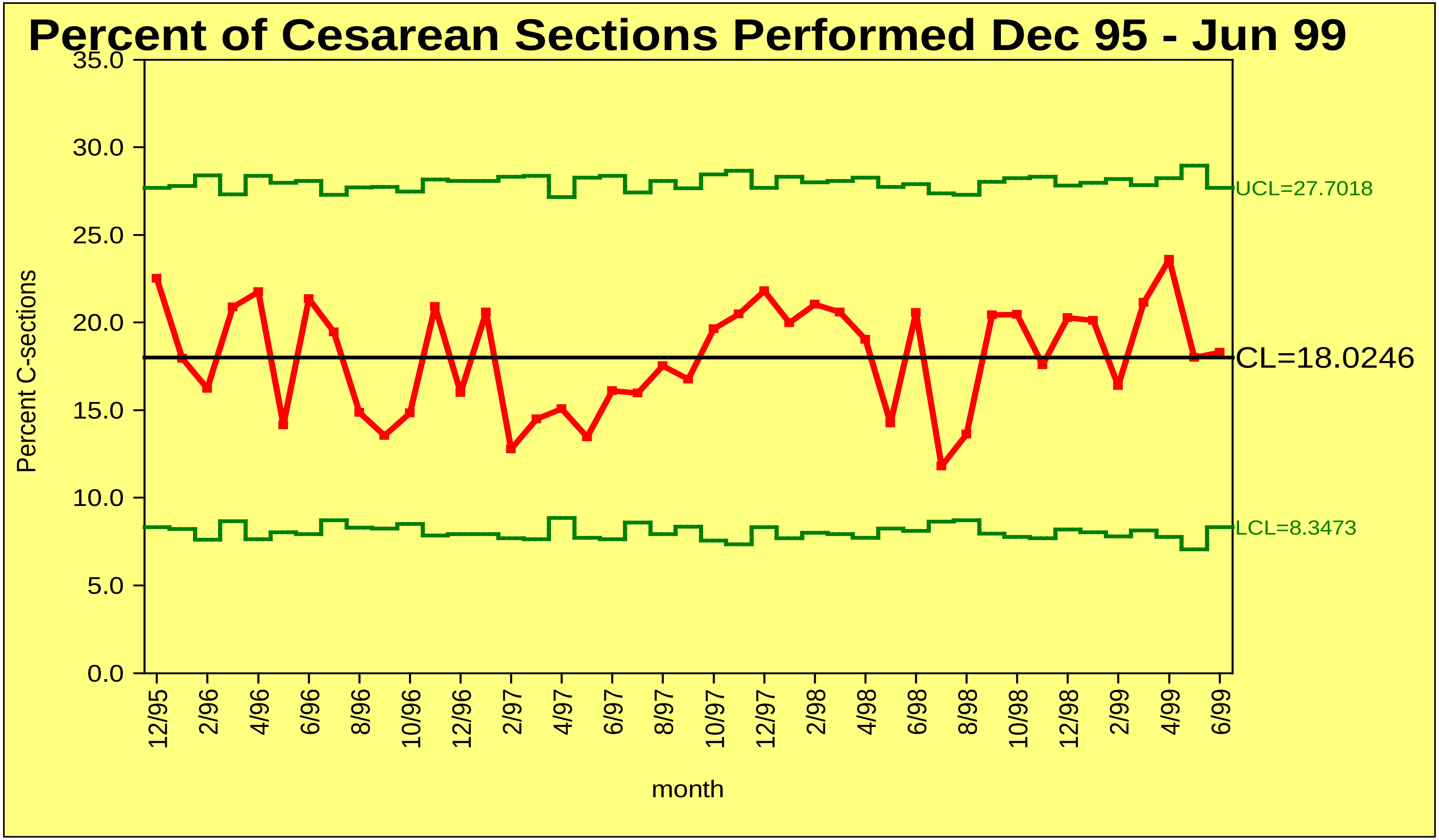
- Do you and the leaders of your organization evaluate these measures according the criteria for common and special causes of variation?



- If not, what criteria do you use to determine if data are improving or getting worse?

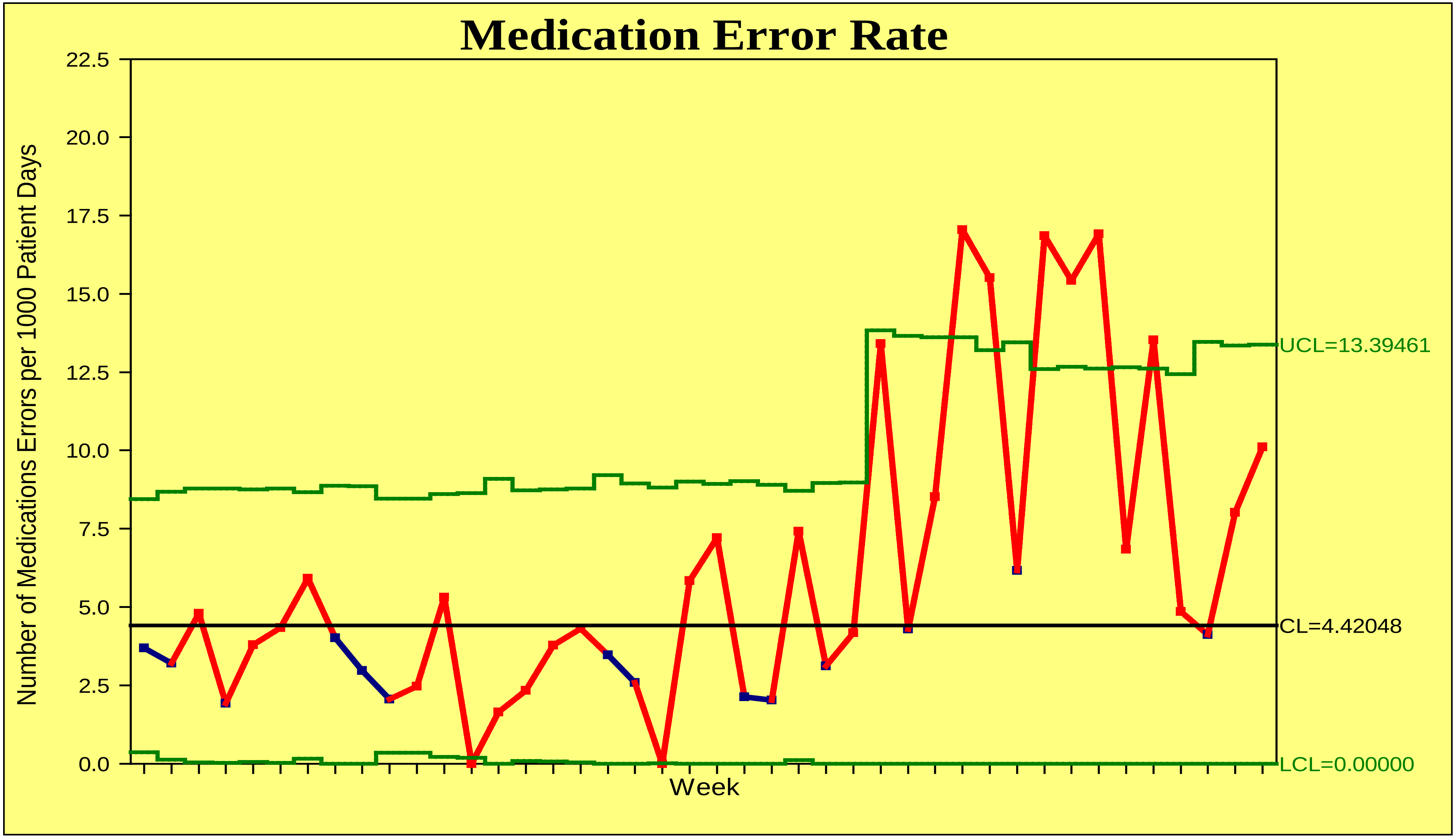
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

Common Cause Variation



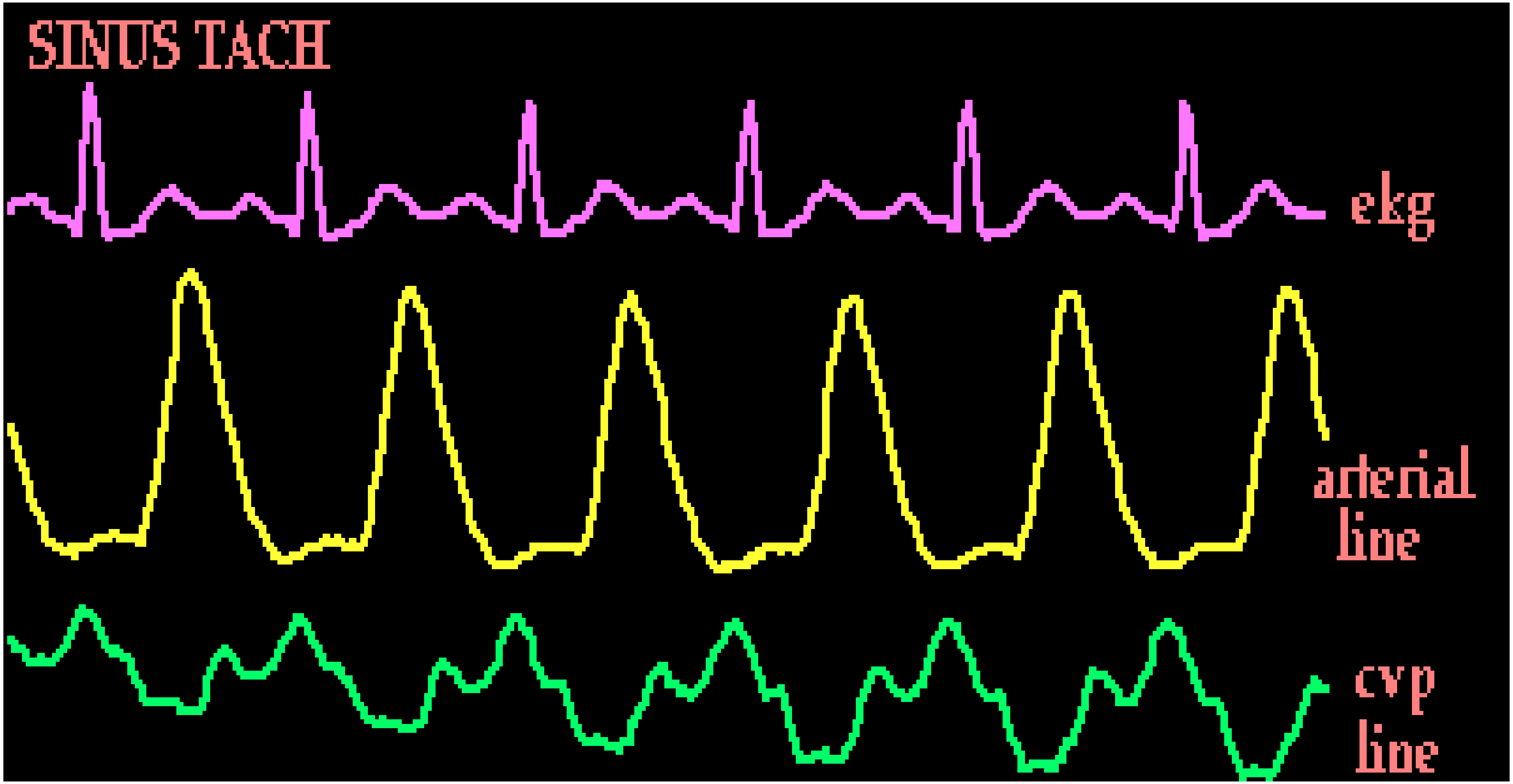
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

Special Cause Variation



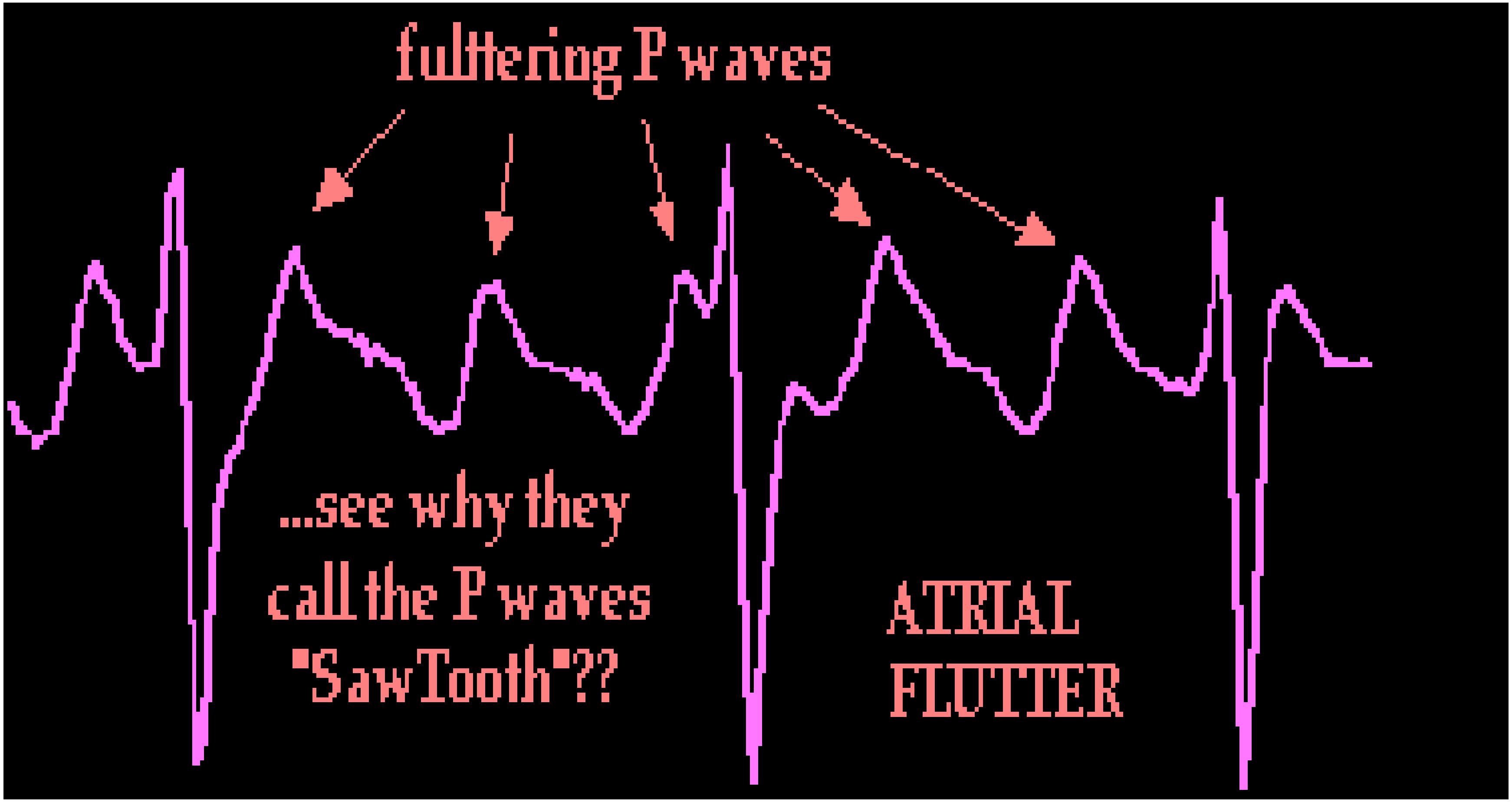
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

Normal Sinus Rhythm (a.k.a. Common Cause Variation)



There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

Atrial Flutter Rhythm (a.k.a. Special Cause Variation)



How do we analyze variation for quality improvement?

Run and ***Control Charts*** are the best tools to determine if our improvement strategies have had the desired effect.

How many data points do I need to make a chart?

<u>Typically</u> *you should have between 15 – 20* data points before constructing a chart

15 – 20 patients

15 – 20 days

15 – 20 weeks

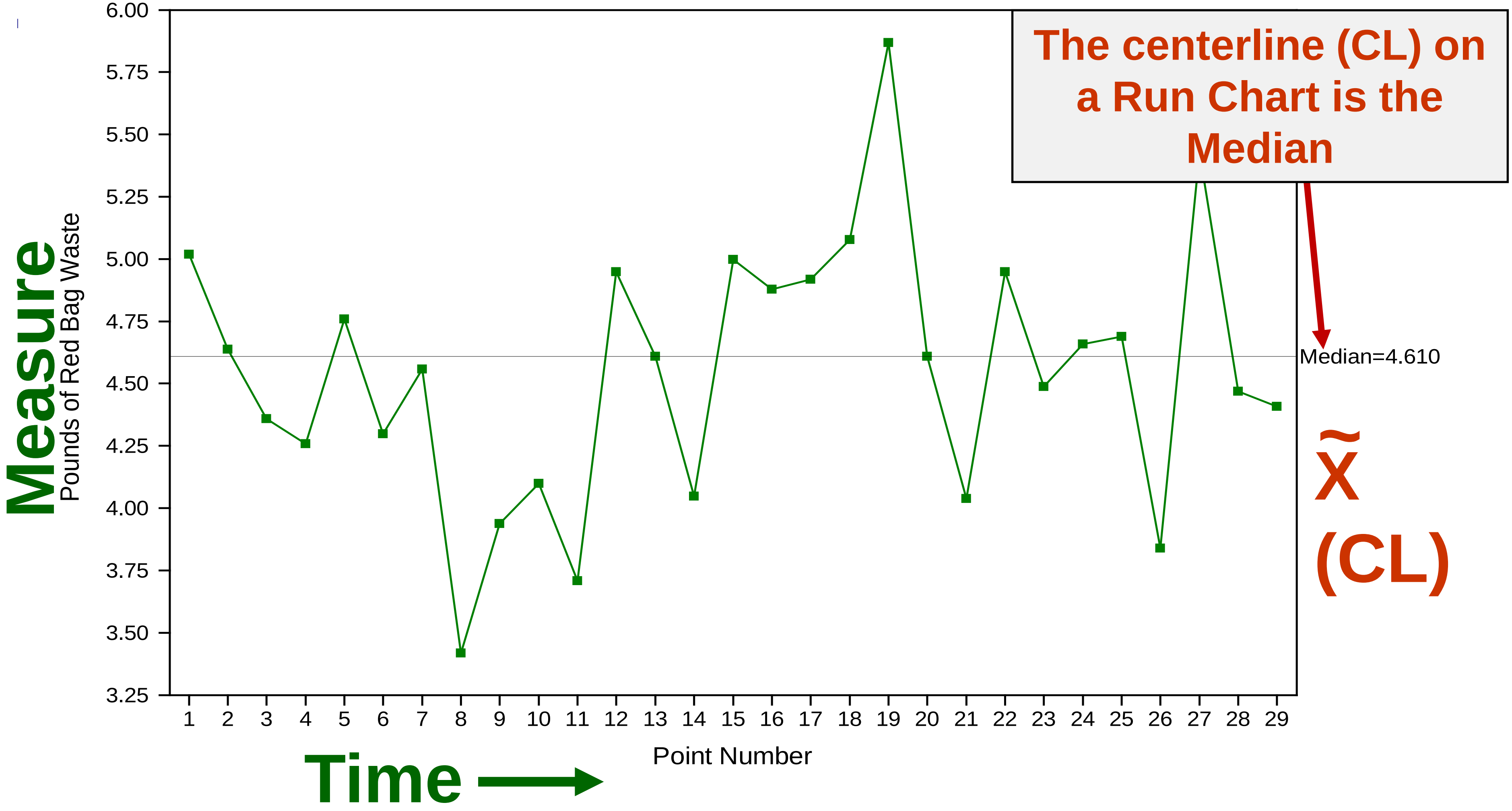
15 – 20 months

15 - 20 quarters…?

Guiding Principles for Creating Charts

- If you have less than 10 data points, make a simple line graph to see where the data points are going.
- If you have 10 and 12 data points you can convert the simple line graph to a run chart (place the median on the line graph and apply the run chart rules).
- When you have 12 -15 data points you can calculate a control chart but you should note that the control limits are "trial control limits."

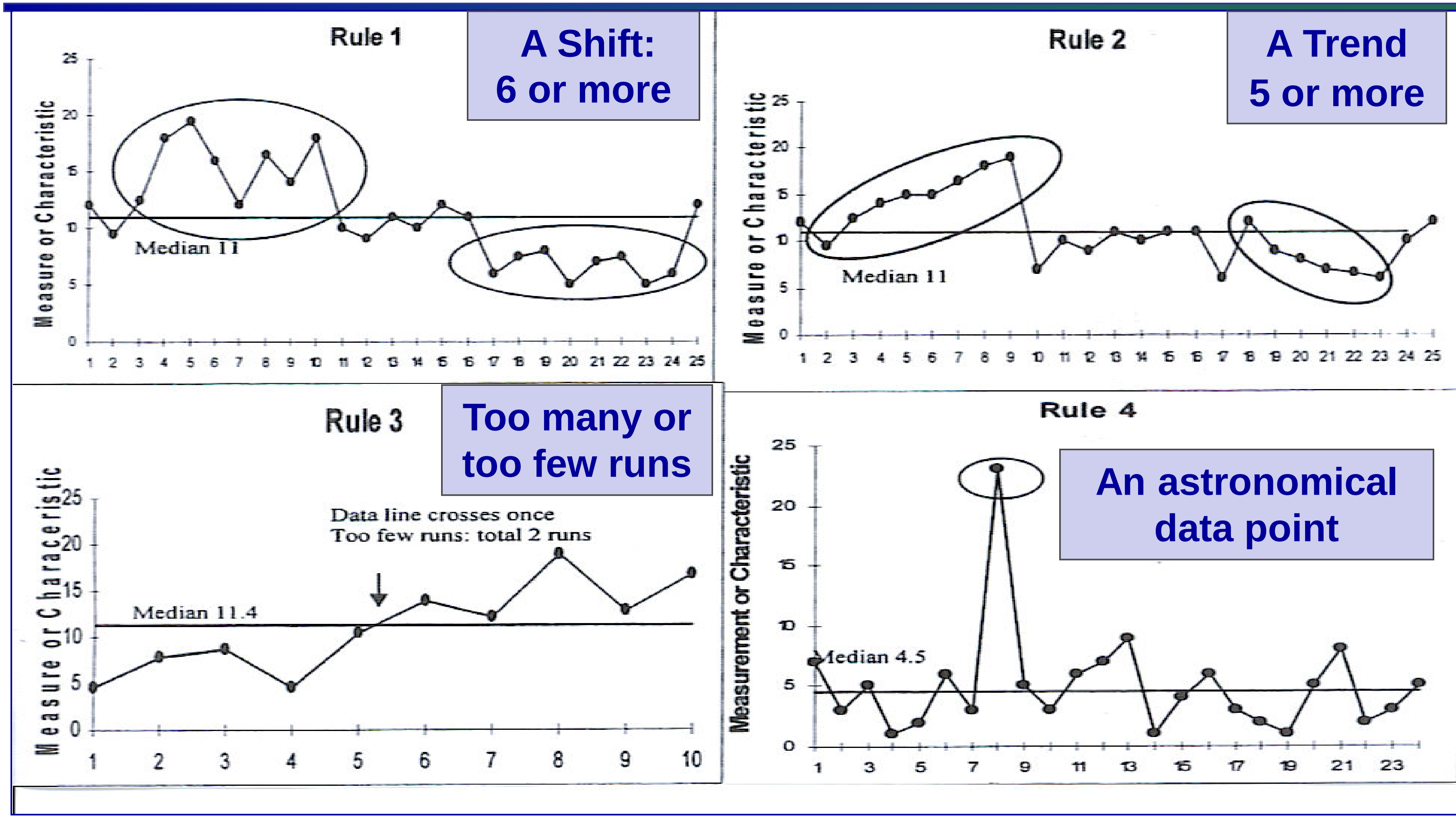
Elements of a Run Chart



Four simple run rules are used to determine if special cause variation is present

©Copyright 2012 IHI/R. Lloyd

Non-Random Rules for Run Charts



Source: The Data Guide by L. Provost and S. Murray, Austin, Texas, February, 2007: p3-10.

©Copyright 2012 IHI/R. Lloyd

Now, let’s go…

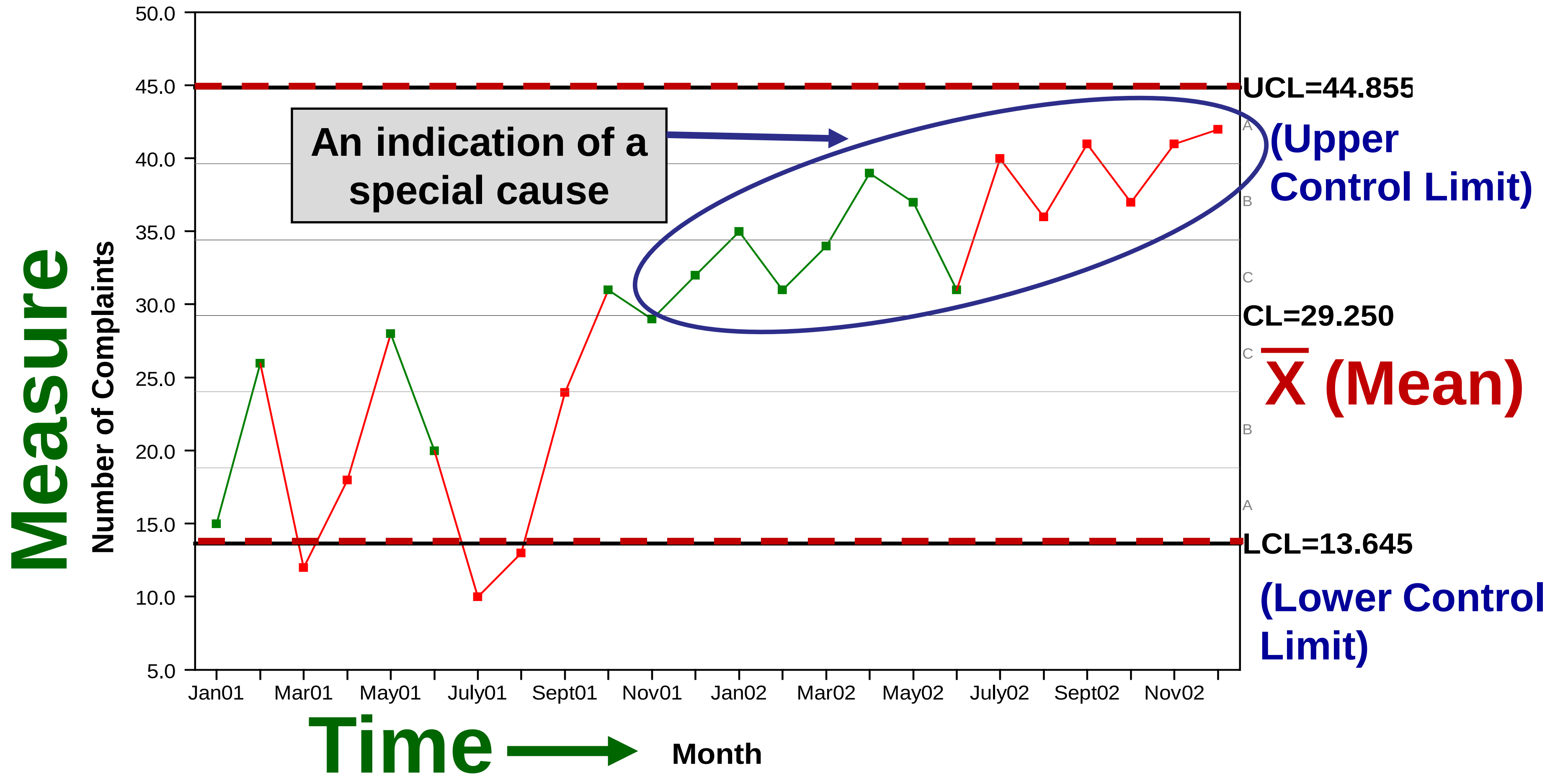
Why are Control Charts preferred over Run Charts?

Because Control Charts…

1. Are more sensitive than run charts
   - A run chart cannot detect special causes that are due to point-to-point variation (median versus the mean)
   - Tests for detecting special causes can be used with control charts
2. Have the added feature of control limits, and zones which allow us to determine if the process is stable (common cause variation) or not stable (special cause variation).
3. Can be used to define *process capability*.
4. Allow us to more accurately predict process behavior and future performance.

©Copyright 2012 IHI/R. Lloyd

Elements of a Control (Shewhart) Chart



©Copyright 2012 IHI/R. Lloyd

Six consecutive points increasing (trend up) or

Rules for Detecting Special Causes

©Copyright 2012 IHI/R. Lloyd

Notes on Special Cause Rules

Rule #1: 1 point outside the +/- 3 sigma limits

A point exactly on a control limit is not considered outside the limit . When there is not a lower or upper control limit Rule 1 does not apply to the side missing the limit.

Rule #2: 8 successive consecutive points above (or below) the centerline

A point exactly on the centerline does not cancel or count towards a shift.

Rule #3: 6 or more consecutive points steadily increasing or decreasing

Ties between two consecutive points do not cancel or add to a trend. When control charts have varying limits due to varying numbers of measurements within subgroups, then rule #3 should not be applied.

Rule #4: 2 out of 3 successive points in Zone A or beyond

When there is not a lower or upper control limit Rule 4 does not apply to the side missing a limit.

Rule #5: 15 consecutive points in Zone C on either side of the centerline

This is known as "hugging the centerline"

©Copyright 2012 IHI/R. Lloyd

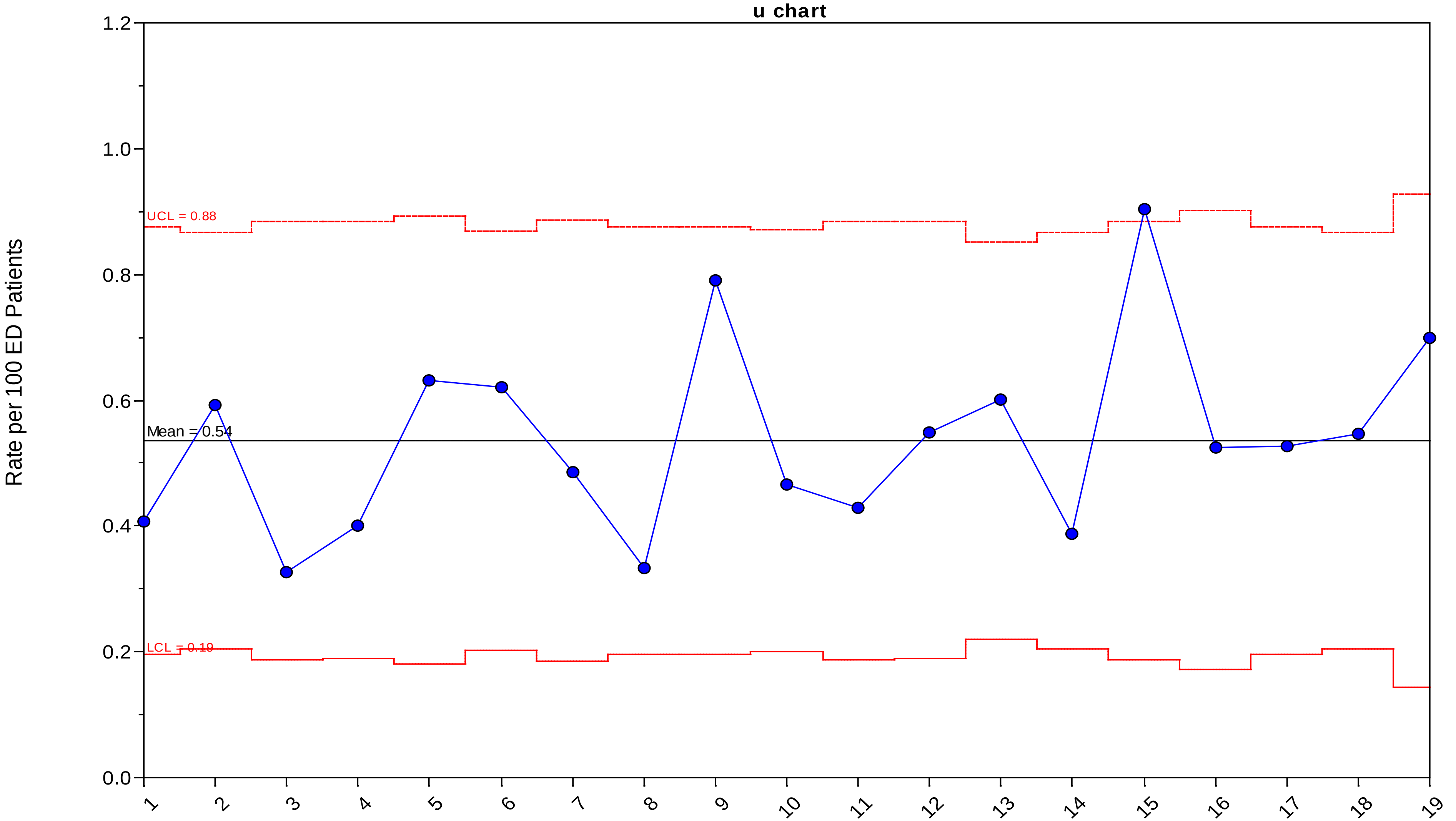
A Quick Test to Identify Special Causes

©Copyright 2012 IHI/R. Lloyd

Is there a Special Cause on this chart?

Unplanned Returns to Ed w/in 72 Hours

Month	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
ED/100	41.78	43.89	39.86	40.03	38.01	43.43	39.21	41.90	41.78	43.00	39.66	40.03	48.21	43.89	39.86	36.21	41.78	43.89	31.45
Returns	17	26	13	16	24	27	19	14	33	20	17	22	29	17	36	19	22	24	22

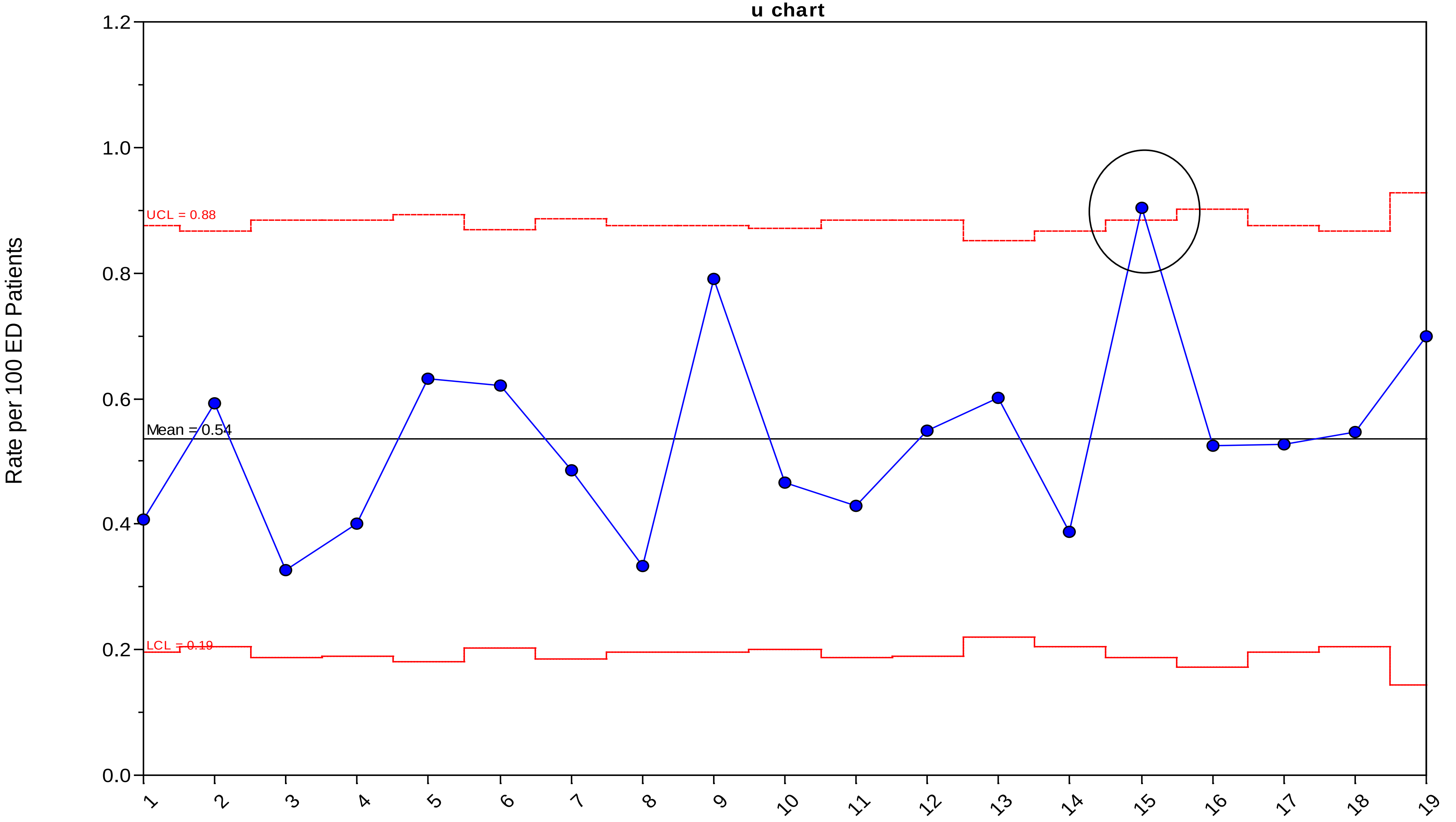


©Copyright 2012 IHI/R. Lloyd

Special Cause: Point Outside the UCL

Unplanned Returns to Ed w/in 72 Hours

Month	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
ED/100	41.78	43.89	39.86	40.03	38.01	43.43	39.21	41.90	41.78	43.00	39.66	40.03	48.21	43.89	39.86	36.21	41.78	43.89	31.45
Returns	17	26	13	16	24	27	19	14	33	20	17	22	29	17	36	19	22	24	22

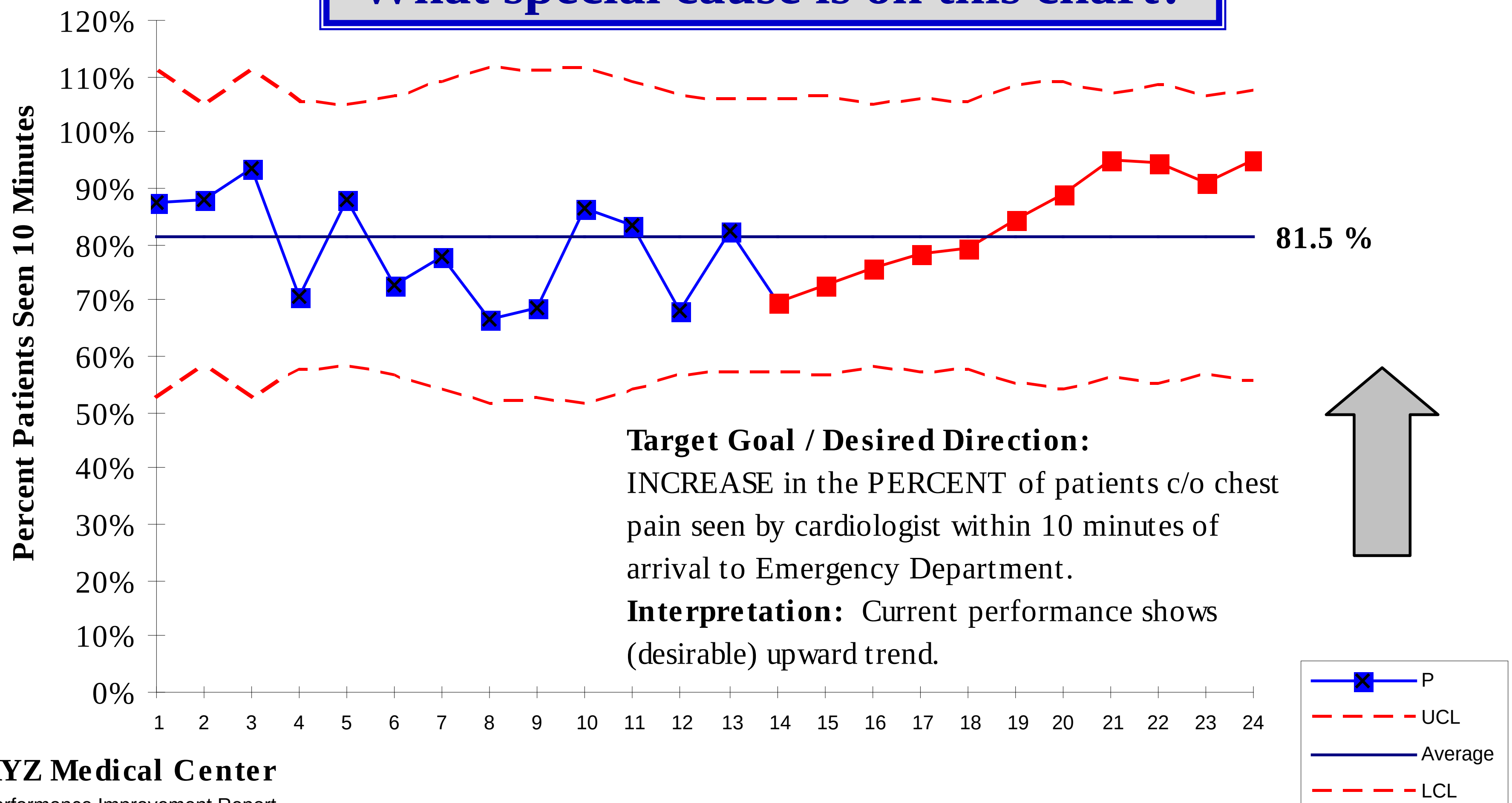


©Copyright 2012 IHI/R. Lloyd

PERCENT PATIENTS C/O CHEST PAIN SEEN BY CARDIOLOGIST WITHIN 10 MINUTES OF ARRIVAL TO ED

EXAMPLE CHART

What special cause is on this chart?



Target Goal / Desired Direction:
INCREASE in the PERCENT of patients c/o chest pain seen by cardiologist within 10 minutes of arrival to Emergency Department.

Interpretation: Current performance shows (desirable) upward trend.

XYZ Medical Center

Performance Improvement Report

March 25, 2004

Fictitious data for educational purposes

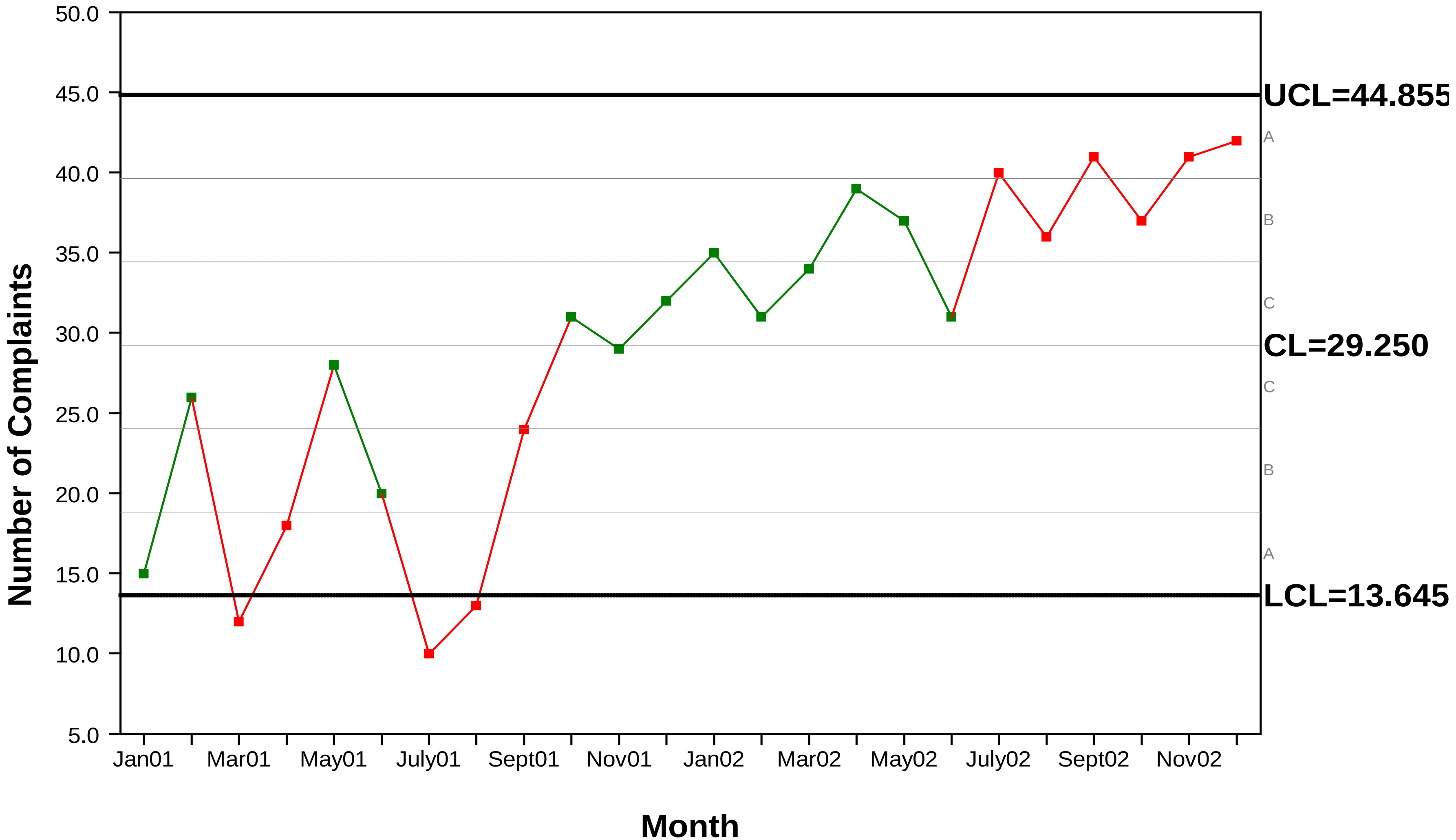
24 Weeks: October 2003 -- March 2004

p-chart, possible range 0-100%

Number of Patient Complaints by Month

(XmR chart)

Are there any special causes present? If so, what are they?

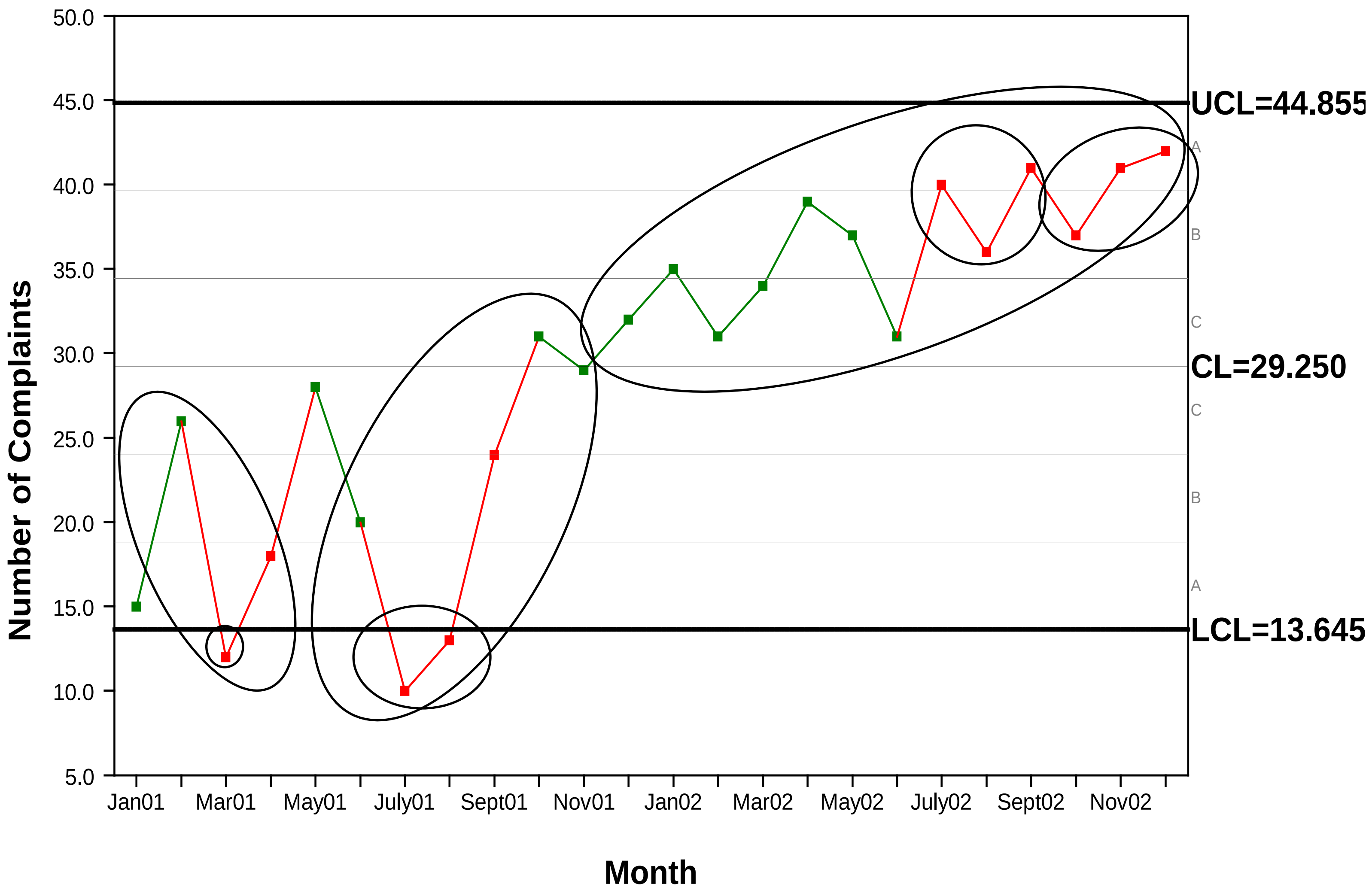


©Copyright 2012 IHI/R. Lloyd

Number of Patient Complaints by Month

(XmR chart)

Are there any special causes present? If so, what are they?

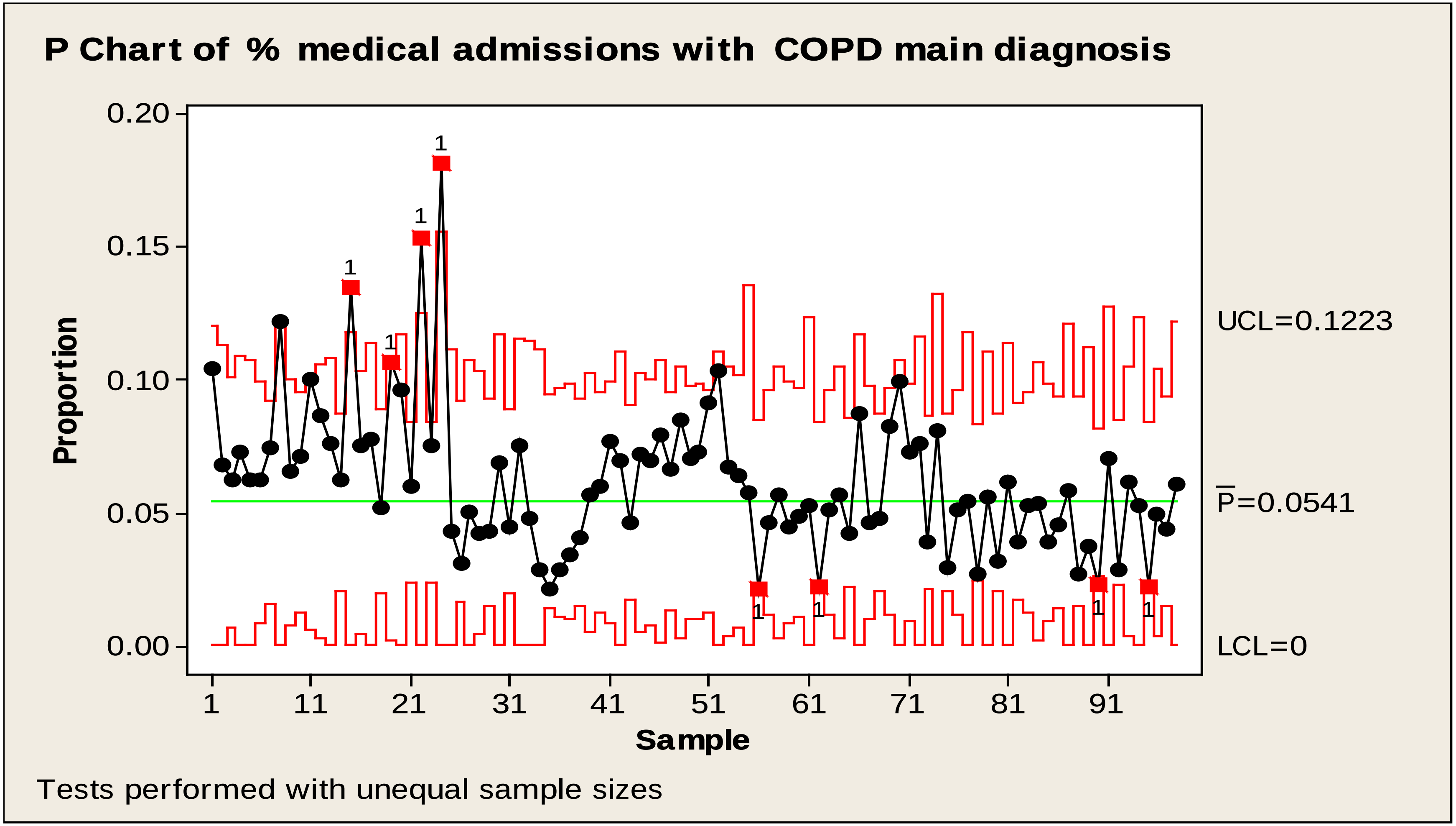


©Copyright 2012 IHI/R. Lloyd

What do you conclude about this chart?

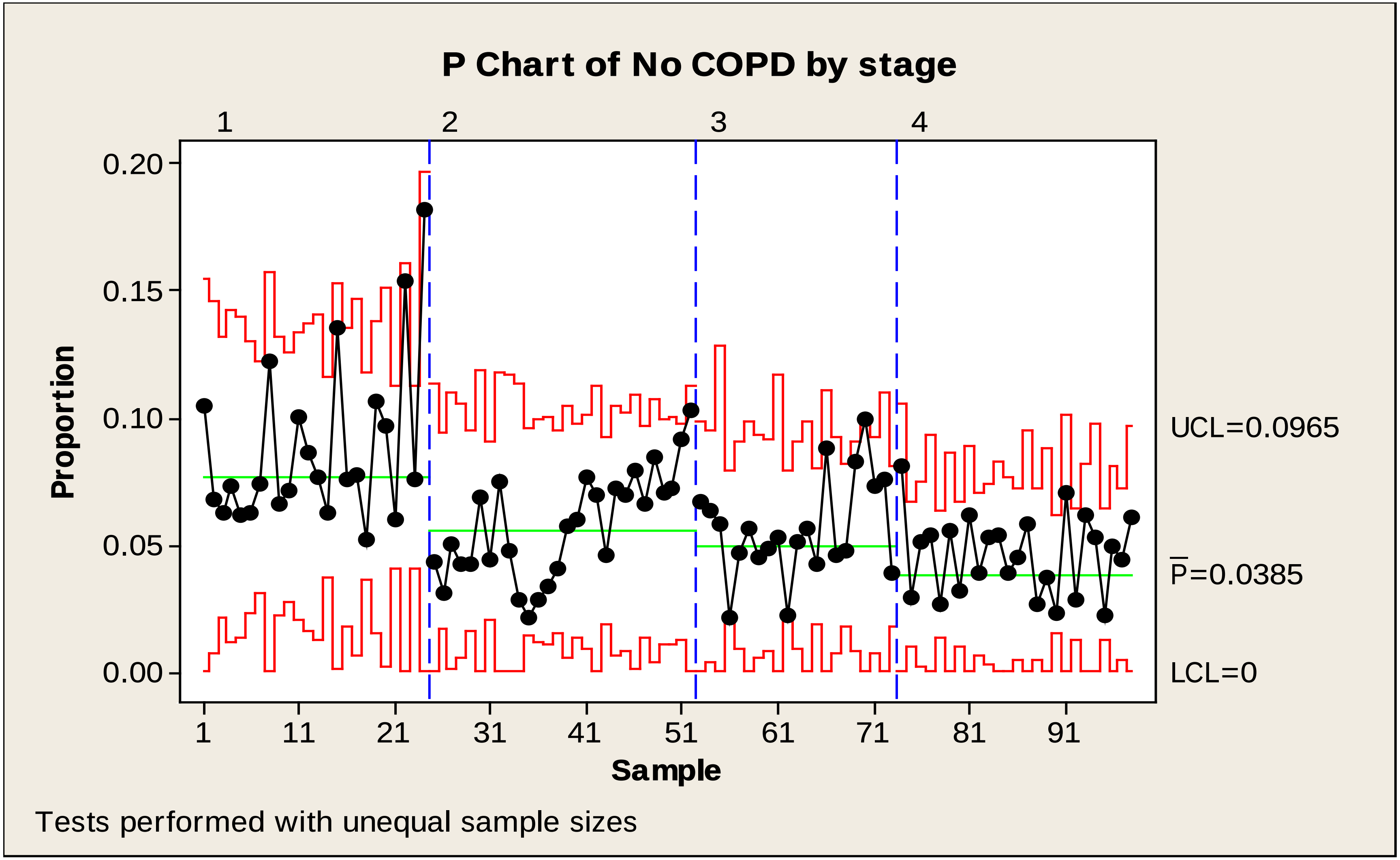
Do you see any special causes?

What questions would you ask?



©Copyright 2012 IHI/R. Lloyd

This is actually four different charts.
The data should have been stratified by severity.

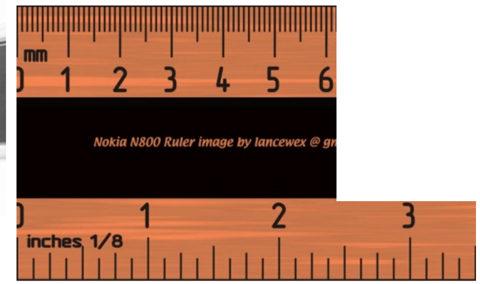


©Copyright 2012 IHI/R. Lloyd

©Copyright 2012 IHI/R. Lloyd

The choice of a Control Chart depends on the Type of Data you have collected

Variables Data

Attributes Data

Defectives

(occurrences plus non-occurrences)

Nonconforming Units

Defects

(occurrences only)

Nonconformities

©Copyright 2012 IHI/R. Lloyd

There Are 7 Basic Control Charts

Variables Charts

- $\overline{X}$ & R chart
  (average & range chart)
- $\overline{X}$ & S chart
  (average & SD chart)
- XmR chart
  (individuals & moving range chart)

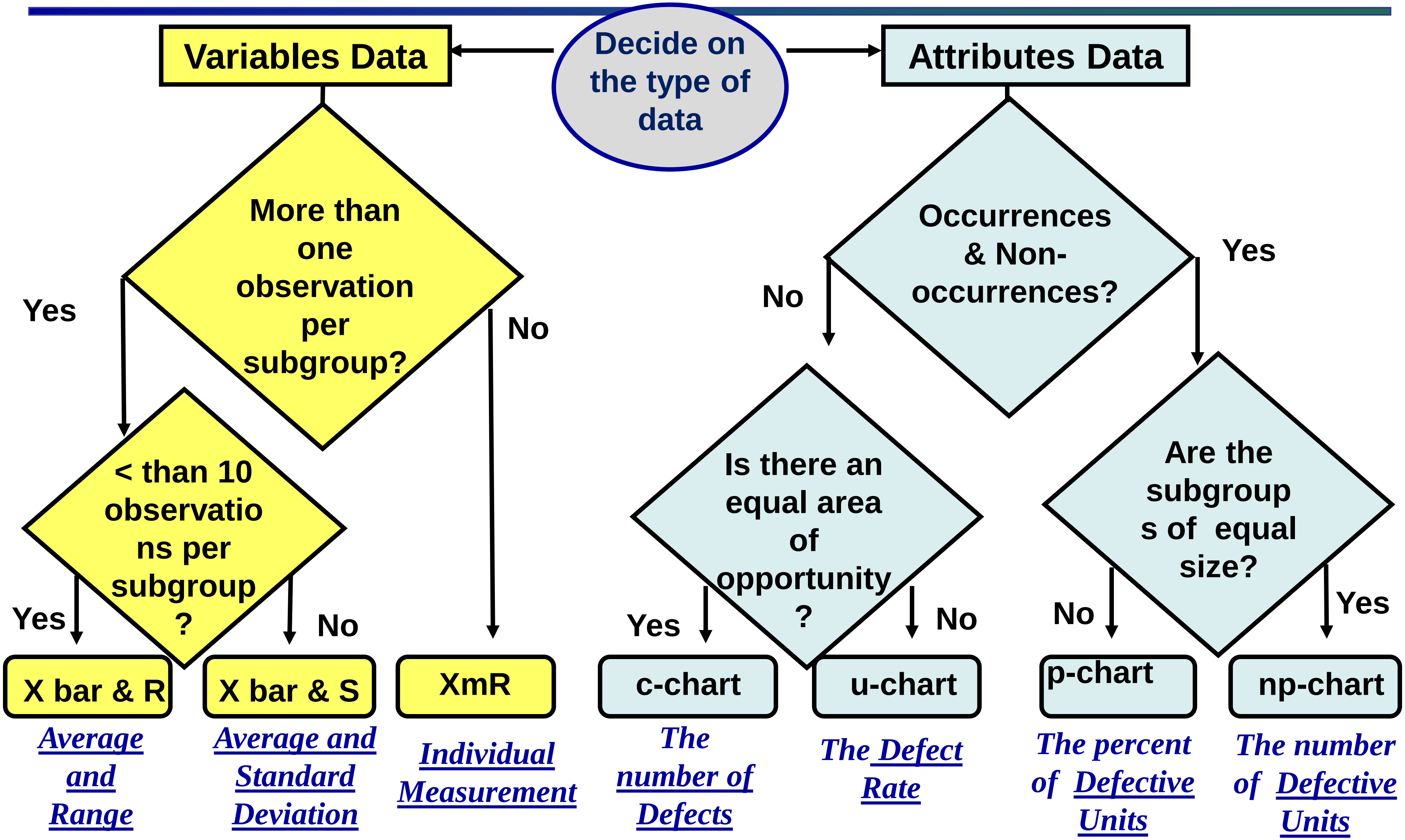
Attributes Charts

- p-chart
  (proportion or percent of defectives)
- np-chart
  (number of defectives)
- c-chart
  (number of defects)
- u-chart
  (defect rate)

©Copyright 2012 IHI/R. Lloyd

The Control Chart Decision Tree

Source: Carey, R. and Lloyd, R. *Measuring Quality Improvement in Healthcare: A Guide to Statistical Process Control Applications*. ASQ Press, Milwaukee, WI, 2001.



©Copyright 2012 IHI/R. Lloyd

Key Terms for Control Chart Selection

Subgroup	**Observation**	**Area of Opportunity**
How you organize you data (e.g., by day, week or month)	The actual value (data) you collect	Applies to all attributes or counts charts
The label of your *horizontal axis*	The label of your *vertical axis*	Defines the area or frame in which a defective or defect can occur
Can be patients in chronological order	May be single or multiple data points	Can be of equal or unequal sizes
Can be of equal or unequal sizes	Applies to all the charts	
Applies to all the charts		

©Copyright 2012 IHI/R. Lloyd

Exercise
You Make the Call on these HEN Measures

Measure	Subgroup?	Type of Data?	Type of Chart?
The daily total number of ED patients who have at least one medication order entered using computerized provider order entry (CPOE).		**V or A**	
The number of central line insertions each week during which all elements of the bundle were followed divided by the total number of central line insertions that week		**V or A**	
The weekly number of catheter-associated urinary tract infections per 1000 urinary catheter days		**V or A**	
The total number of patient falls each month (with or without injury to the patient and whether or not assisted by a staff member) divided by the total patient days for the month		**V or A**	
The number of hand hygiene performed consistent with guidelines divided by the total number of hand hygiene observation opportunities		**V or A**	

©Copyright 2012 IHI/R. Lloyd

Exercise
You Make the Call on these HEN Measures

Measure	Subgroup?	Type of Data?	Type of Chart?
The daily total number of ED patients who have at least one medication order entered using computerized provider order entry (CPOE).	**Day**	**V or A**	**XmR**
The number of central line insertions each week during which all elements of the bundle were followed divided by the total number of central line insertions that week	**Week**	**V or A**	**p-chart**
The weekly number of catheter-associated urinary tract infections per 1000 urinary catheter days	**Week**	**V or A**	**u-chart**
The total number of patient falls each month (with or without injury to the patient and whether or not assisted by a staff member) divided by the total patient days for the month	**Month**	**V or A**	**u-chart**
The number of hand hygiene performed consistent with guidelines divided by the total number of hand hygiene observation opportunities	**?**	**V or A**	**?**

©Copyright 2012 IHI/R. Lloyd

The Quality Measurement Journey

Source: R. Lloyd. Quality Health Care: A Guide to Developing and Using Indicators. Jones and Bartlett Publishers, 2004.

AIM (How good? By when?)

Concept

Measure

Operational Definitions

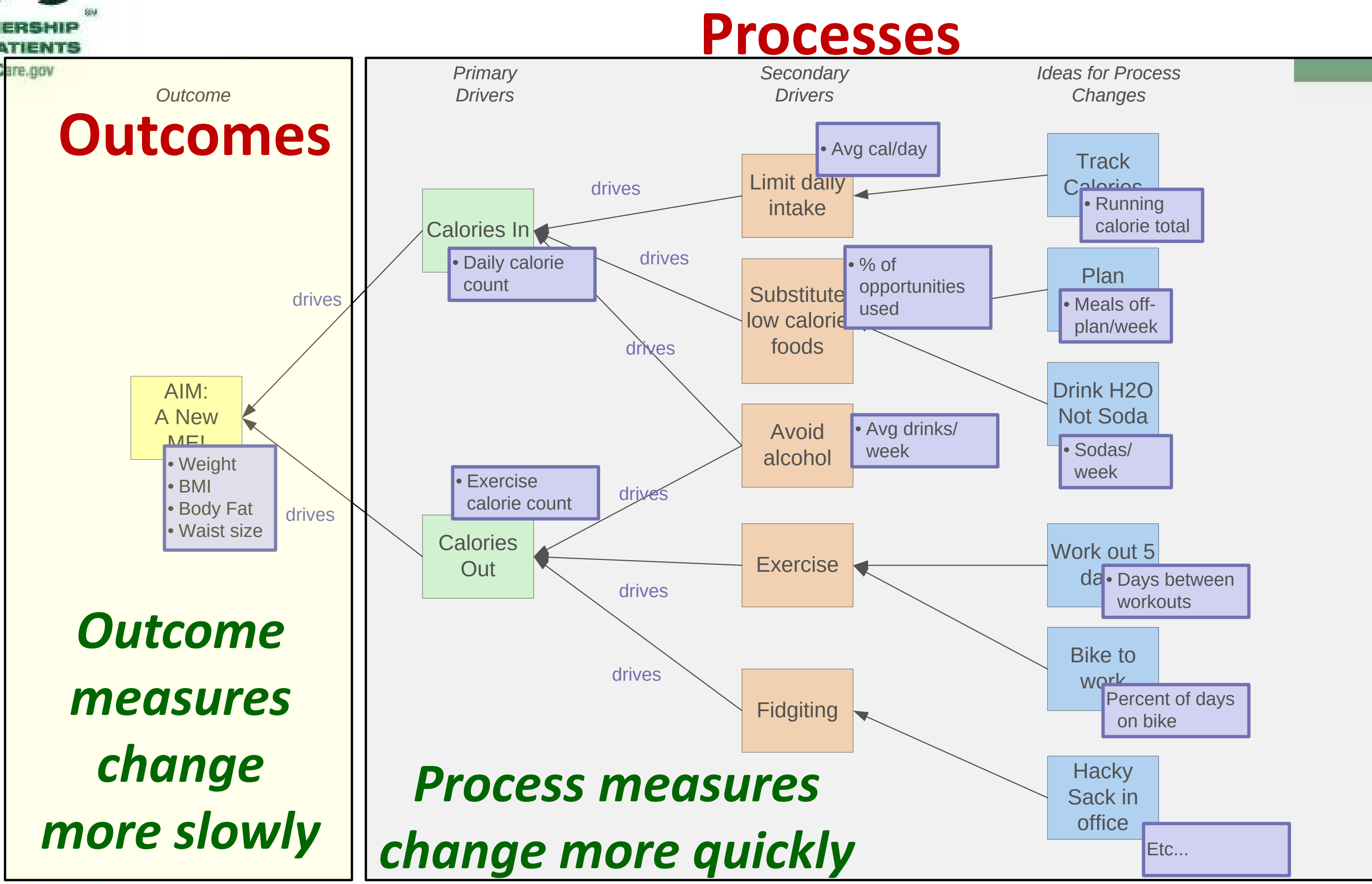
Data Collection Plan

Data Collection

Analysis → **ACTION**

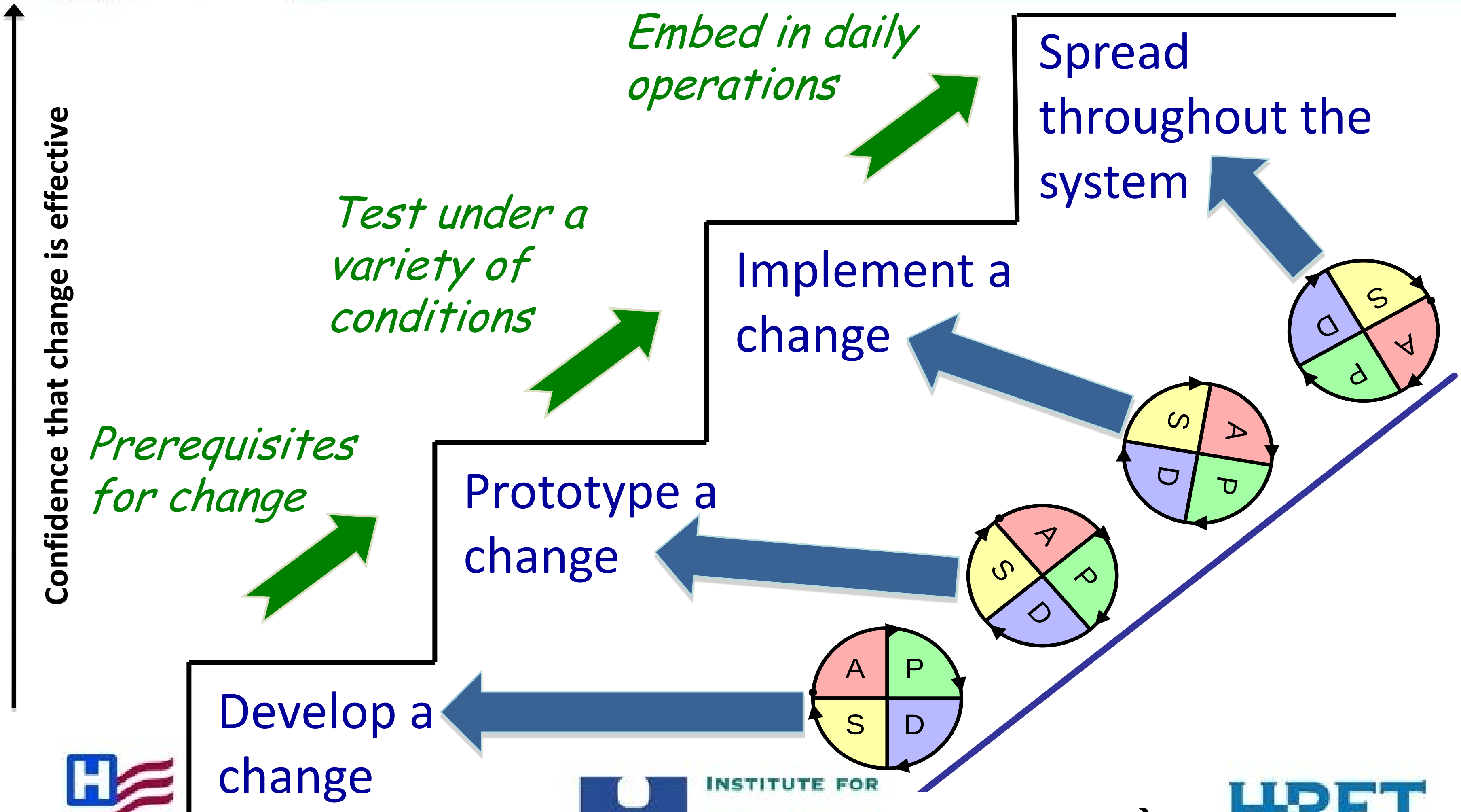
U.S. Department of Health & Human Services
Partnership for Patients
HealthCare.gov
American Hospital Association
Institute for Healthcare Improvement
HRET Health Research & Educational Trust In Partnership with AHA

When will we know that a change produces an improvement?



© Richard Scoville & I.H.I.

The Sequence of Improvement



U.S. Department of Health & Human Services
Partnership for Patients
HealthCare.gov
American Hospital Association
Institute for Healthcare Improvement
HRET
Health Research & Educational Trust
In Partnership with AHA

The Formula for Improvement

Structure

+ Process

+ Culture* = *Outcome*

*Added to Donabedian's original formulation by R. Lloyd and R. Scoville.

Donabedian, A. (1966). "Evaluating the quality of medical care." Milbank Memorial Fund Quarterly 44(3): Suppl:166-206.

A closing thought…

It must be remembered that there is nothing more difficult to plan, more doubtful of success, nor more dangerous to manage than the creation of a new system.

For the initiator has the enmity of all who would profit by the preservation of the old institution and merely lukewarm defenders in those who would gain by the new one.

A closing thought…

It must be remembered that there is nothing more difficult to plan, more doubtful of success, nor more dangerous to manage than the creation of a new system.

For the initiator has the enmity of all who would profit by the preservation of the old institution and merely lukewarm defenders in those who would gain by the new one.

Machiavelli, The Prince, 1513

U.S. Department of Health & Human Services
Partnership for Patients
HealthCare.gov
American Hospital Association
Institute for Healthcare Improvement
HRET Health Research & Educational Trust In Partnership with AHA