Error Analysis & Reduction
Philosophy and Theory

Todd Pawlicki, Ph.D.
Department of Radiation Oncology
Stanford University School of Medicine

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Outline

- Error reduction and quality control
- The ‘system view’ and variation
- Tools for error reduction
- Summary and future directions

Definition of Medical Errors

- The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim

- A factor contributing to errors is the fragmented nature of the health care delivery system – or ‘nonsystem’

To Err Is Human: Building a Safer Health System. 1999: National Academies Press (www.nap.edu/catalog/9728.html).

Definition of Quality

- The quality of a product or service is the loss that product or service causes to the patient after it is used for treatment
- What is the meaning of loss?
  - Loss caused by variability of function
  - Loss caused by harmful side effects
- Quality can not be viewed as a value

G Taguchi. Introduction to Quality Engineering: Designing Quality into Products and Processes. 1986: Asian Productivity Organization.

Error Reduction and Quality

- Both are concerned with reducing the two types of losses that may be caused to the patient after treatment
  - Variability of function
  - Harmful side effects

Health Care Progress

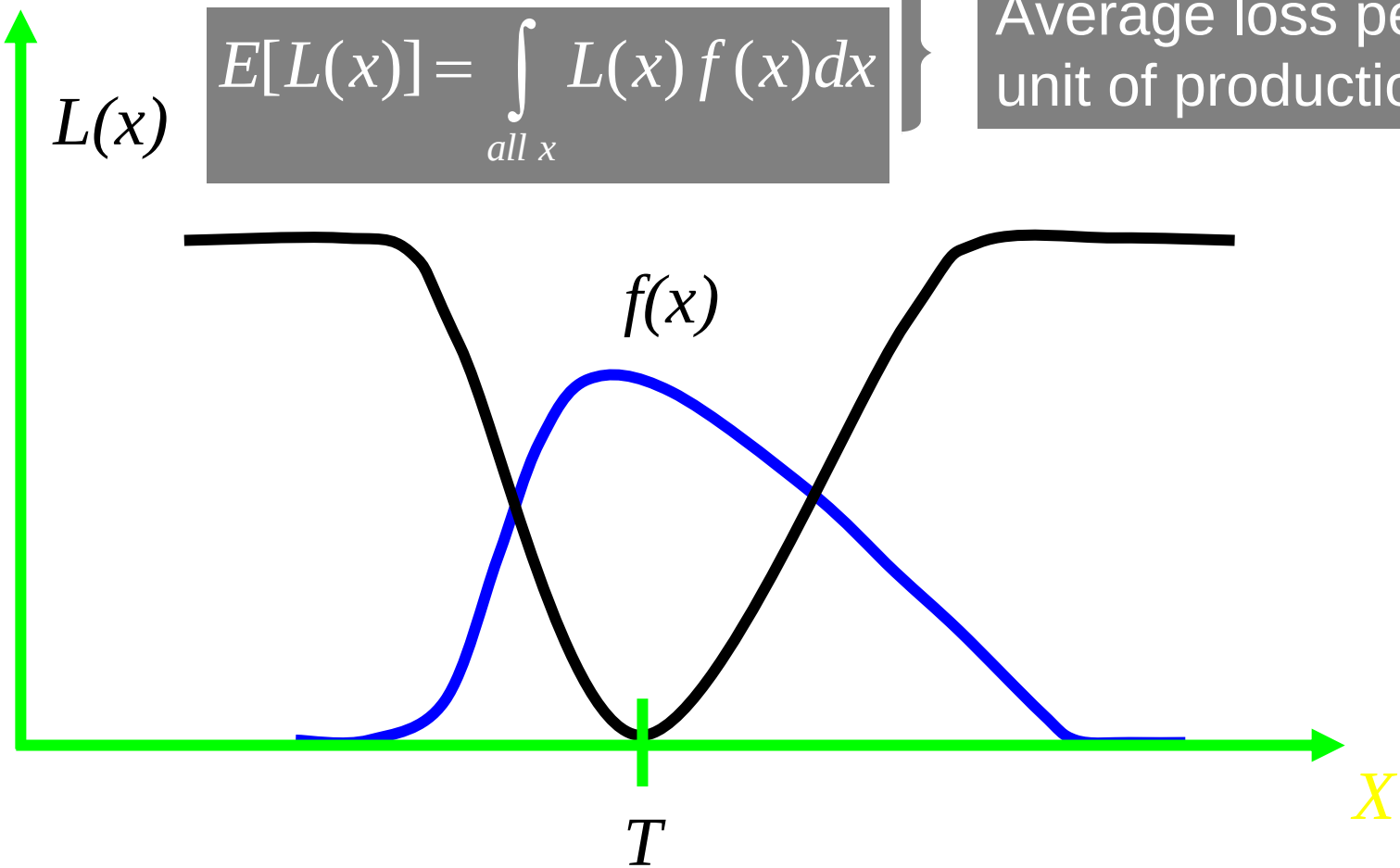
- During the past half-century, progress in health care has been made by medical science and technology breakthroughs
- The quality revolution taking place in medicine will provide new remarkable opportunities to improve health care

B Sadler. To the Class of 2005: Will you be ready for the quality revolution? J on Quality and Patient Safety. 2006;32(1):51-55.

Taguchi Loss Function (TLF)

$$E[L(x)] = \int_{all\ x} L(x)\, f(x)\, dx$$

Average loss per unit of production



TLF Applied to Radiotherapy

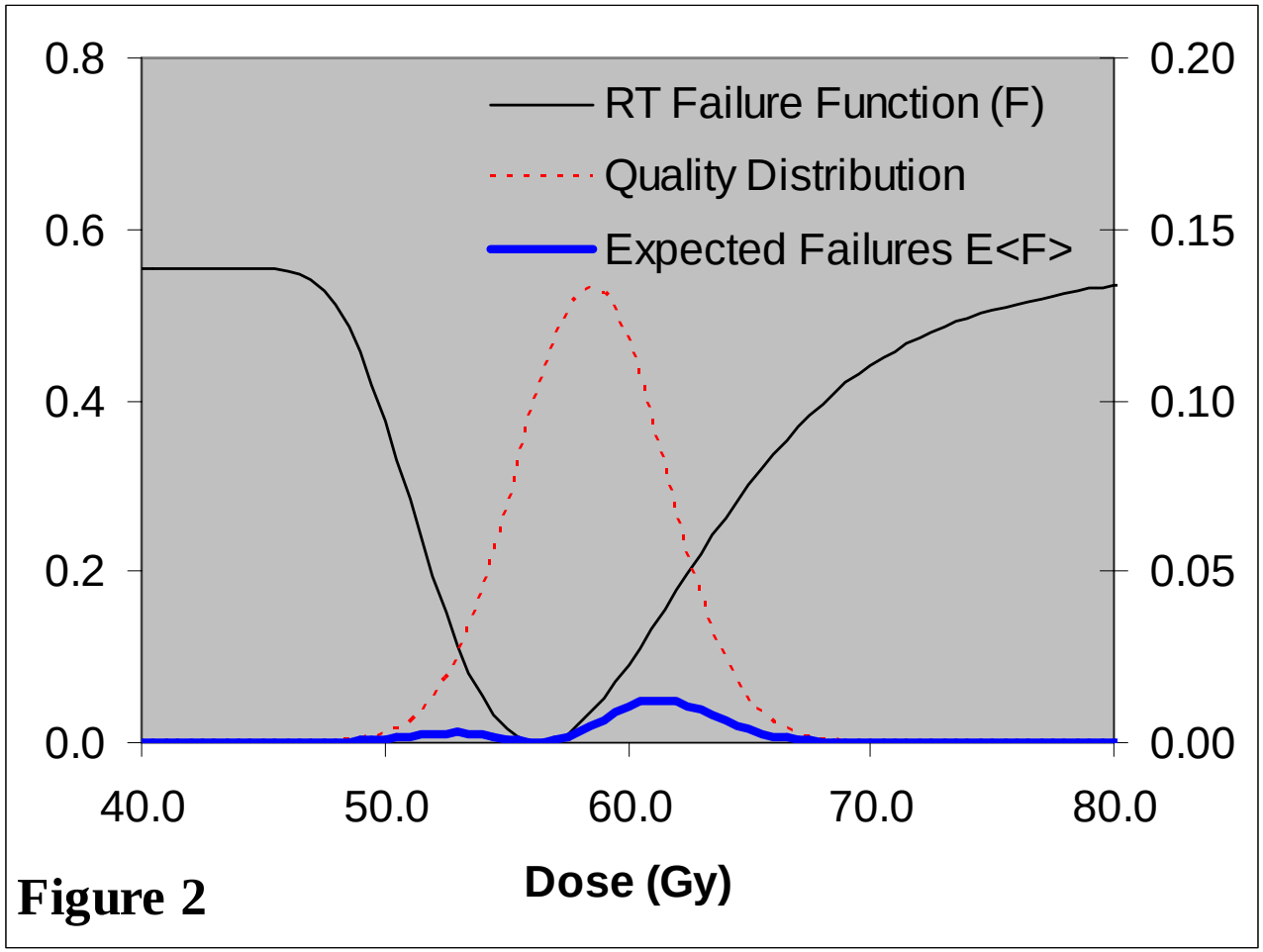


Figure 2

TLF Applied to Radiotherapy

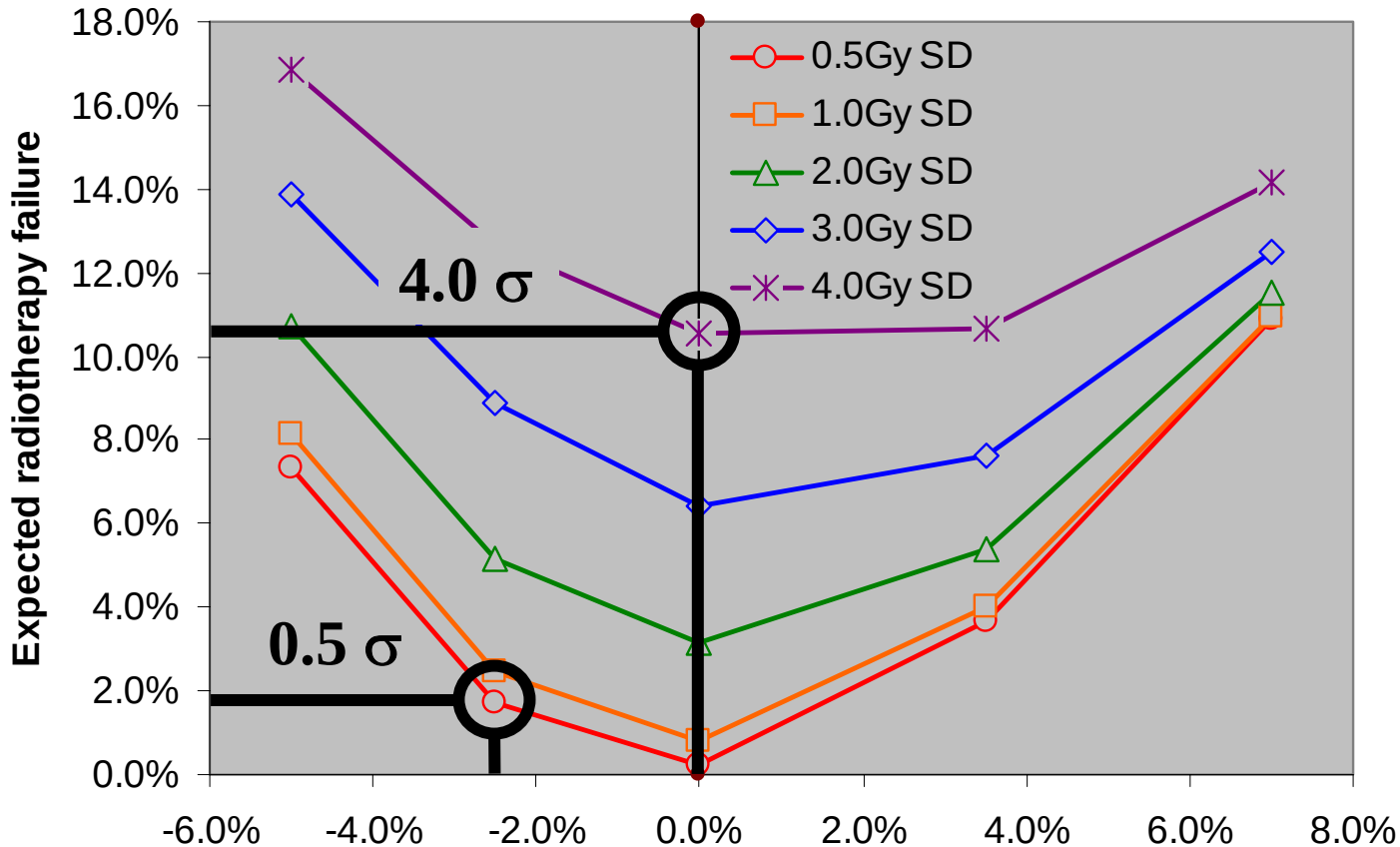


Figure 3

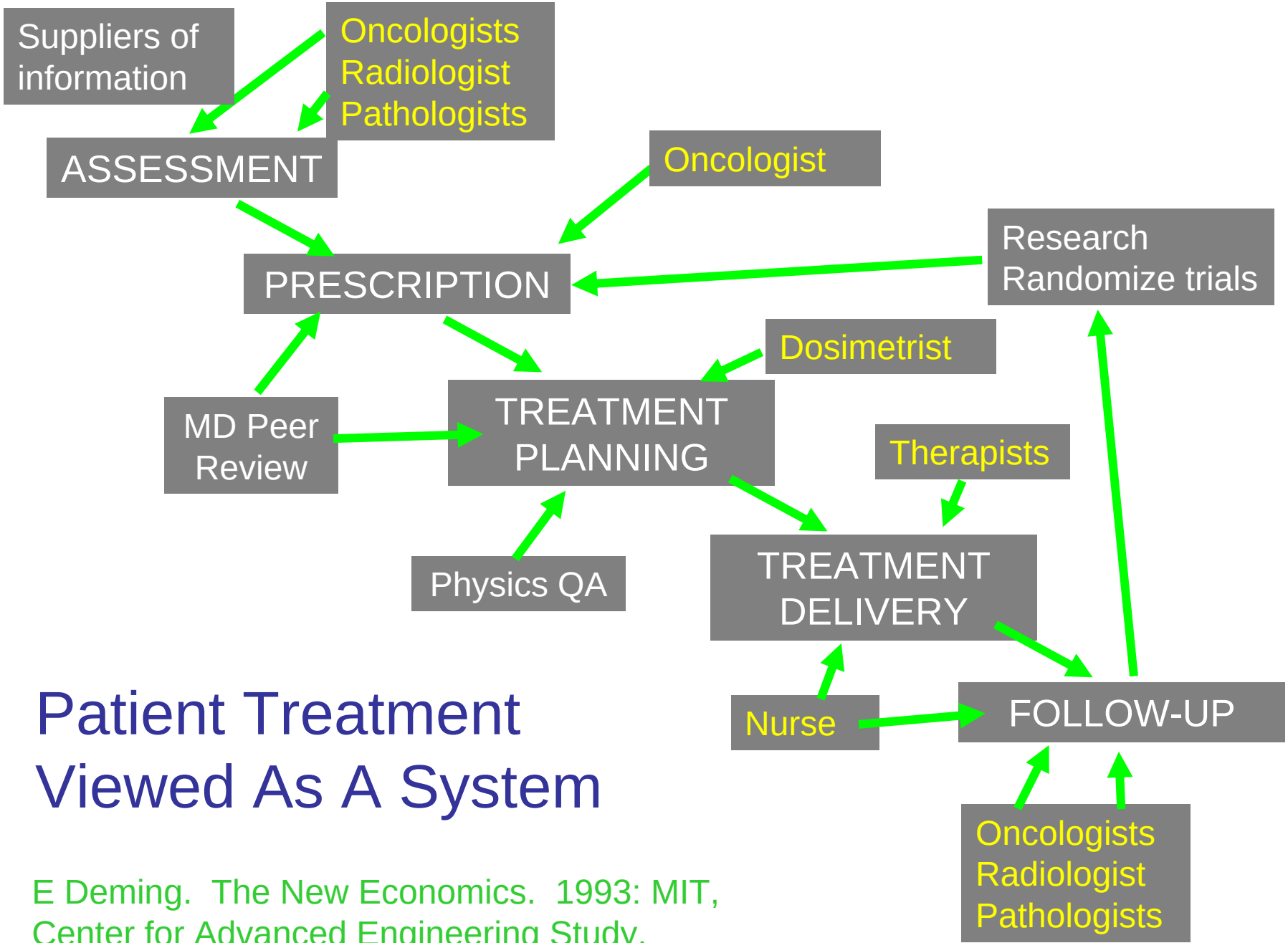
Summary Thus Far

- Error reduction and quality control are intimately related
- Improving quality will reduce errors
- Improving quality may increase survival and decrease complications

The System View and Variation

- Appreciation of a system
  - A network of interdependent components that work together to try to accomplish the aim of the system
- Knowledge of variation
  - Every system (or process) displays variation
  - Variation can be predictable or unpredictable

E Deming. The New Economics. 1993: MIT, Center for Advanced Engineering Study.



Patient Treatment Viewed As A System

E Deming. The New Economics. 1993: MIT, Center for Advanced Engineering Study.

System View

- Every system or process creates data
- Every data set contains noise
  - To detect a signal, first filter out the noise
- Data do not have meaning apart from their context
  - The order in any sequence of observed results helps physical interpretation

D Wheeler. Understanding Variation: The Key to Managing Chaos. 1993: SPC Press.

Knowledge of Variation

- It is easy to appreciate variation in your personal life
  - What about variation in the workplace?
- Failing to appreciate variation in processes can lead to obvious and not so obvious problems

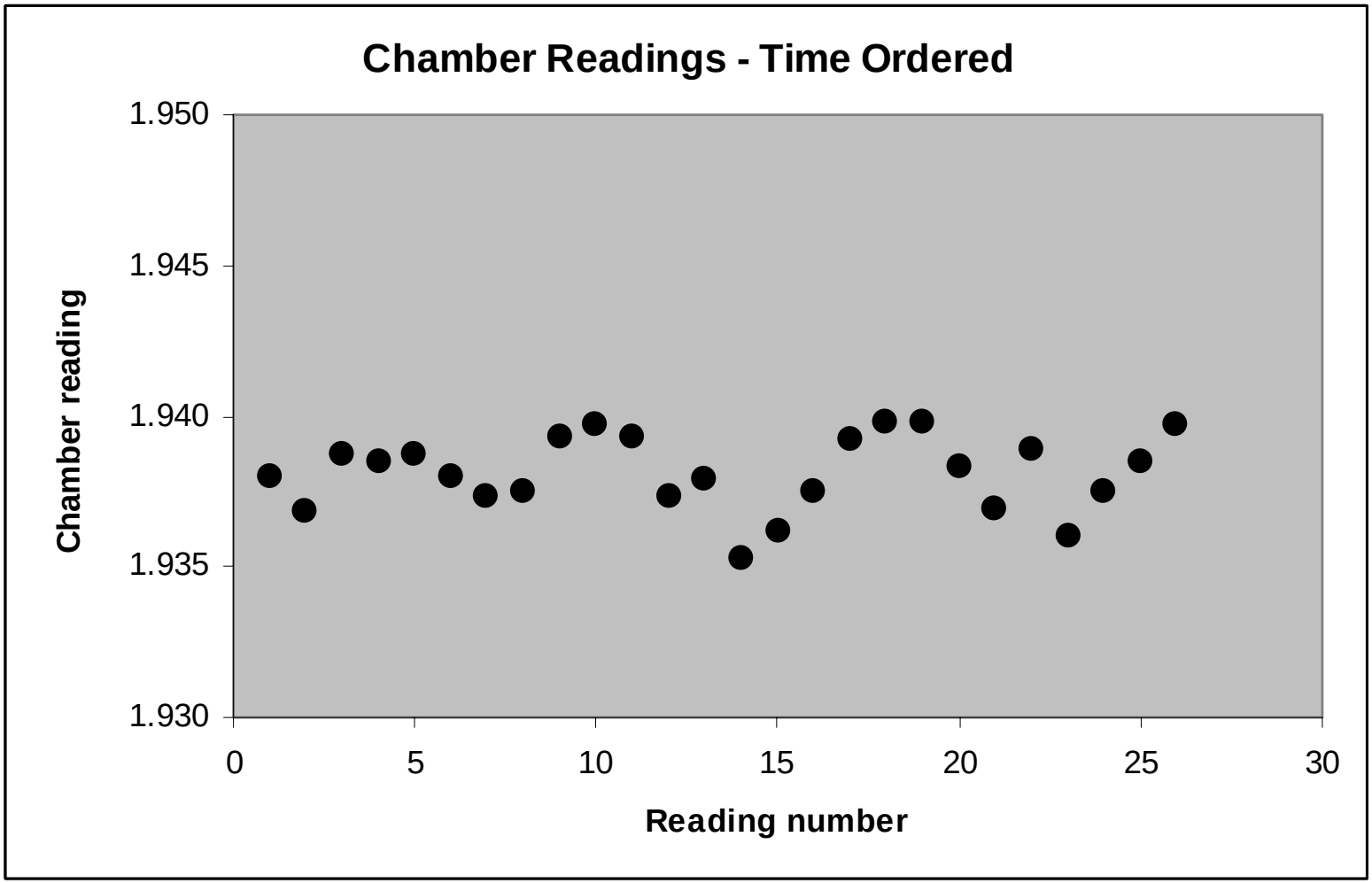
Carey and Lloyd. Measuring Quality Improvement in Healthcare. 2001: ASQ Quality Press Publications.

Without an Understanding of Variation…

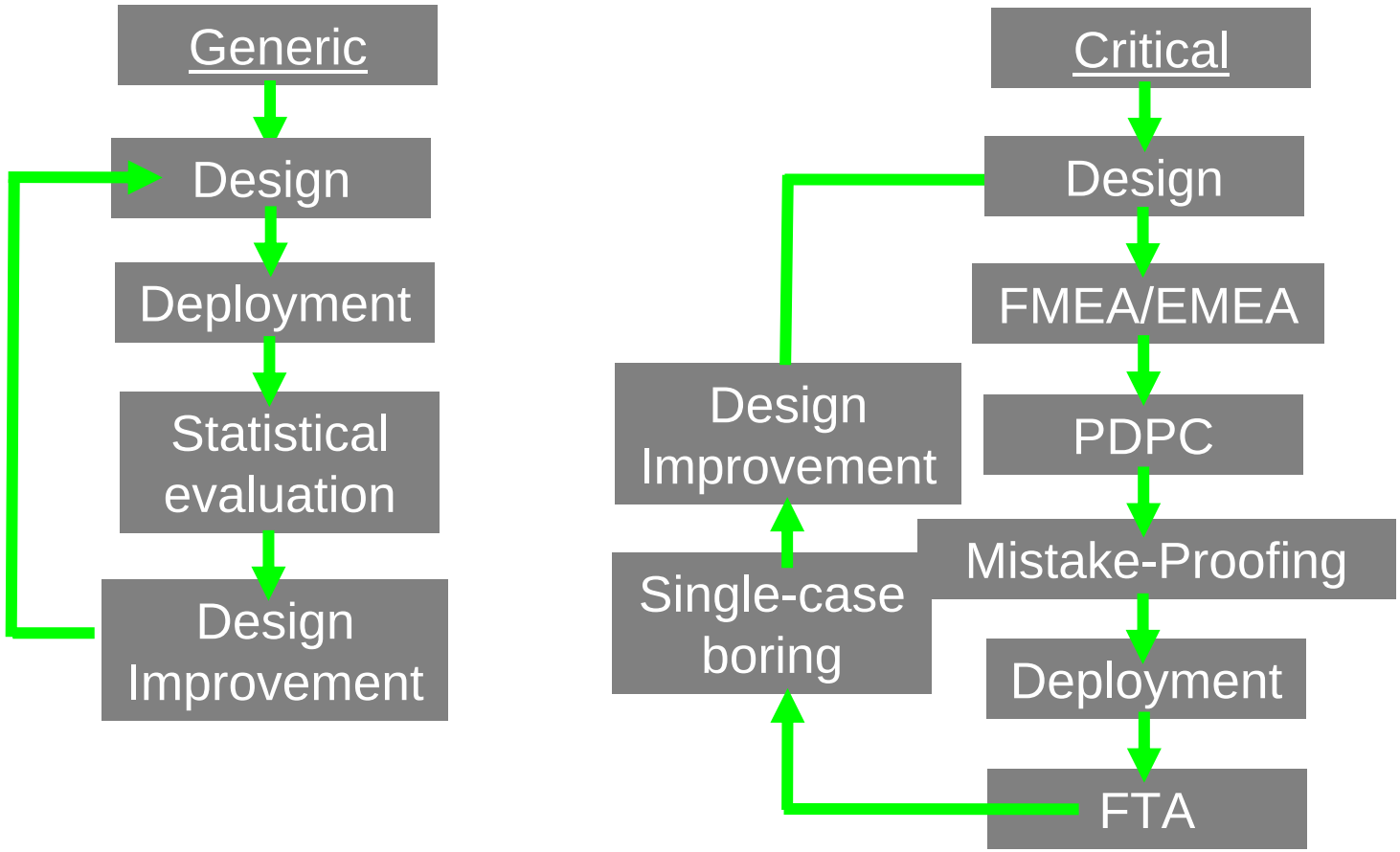
- Difficult to understand past performance
  - No ability to predict the future and make improvements in a process
- Blame or give credit to others for things over which they have little control
- You see trends where none exist

Carey and Lloyd. Measuring Quality Improvement in Healthcare. 2001: ASQ Quality Press Publications.

Importance of Time-Ordered Data



Generic vs Critical Processes



D Hutchison. Chaos Theory, Complexity Theory, and Health Care Quality Management. Quality Progress. 1994:69-72. Figure 1.

Tools For QC & Error Reduction

- Idea Creation (4)
- Cause analysis (3)
- Evaluation and decision-making (2)
- Process analysis (3)
- Project planning and implementation (2)
- Data collection and analysis (7)
- Management and planning tools (7)

http://www.asq.org/learn-about-quality/quality-tools.html (accessed April 21, 2006)

Idea Creation

- Nominal group technique
  - Structured brainstorming session that encourages contributions from everyone
- Affinity diagram
  - Organize a large number of ideas into their natural relationship

Nominal Group Technique

- When to use
  - Ideas are coming slowly
  - Some members are more vocal than others
- General method
  - 10 minutes of individual idea generation
  - Each person states one idea aloud per round
  - Facilitator records each idea on a flipchart
  - After all ideas are out – then discuss each
  - Prioritize the ideas using multi-voting

Affinity Diagram

- When to use
  - Many facts or ideas that seem unrelated
  - Issues seem too complex
- General method
  - Generate ideas – one per notecard
  - Spread all notecards on large surface
  - Group the notecards that are related
  - Discuss patterns of groups – changes are ok
  - Choose a title that captures each group

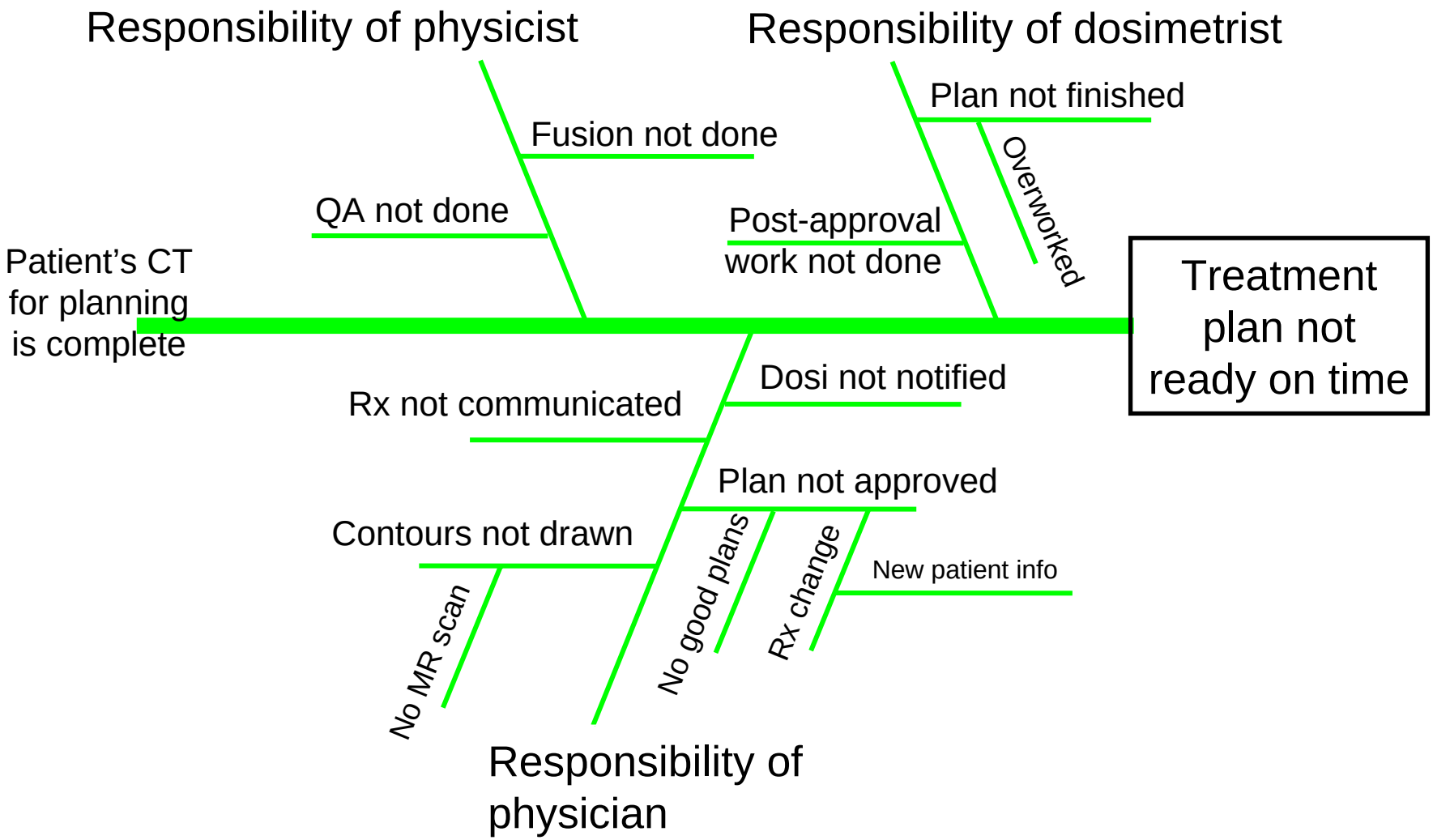
Cause Analysis

- Cause-and-effect (fishbone) diagram
  - Identifies many possible causes for an effect or problem
- Pareto chart
  - Visual depiction of most significant components or situations
- Root cause analysis
  - Study of the original reason for nonconformance with a process

Cause-and-Effect Diagram

- When to use
  - To identify possible causes of a problem
  - Team thinking is in a rut
- General method
  - Describe the problem
  - List categories for causes of the problem
  - List possible causes of the problem
  - Continue to ask, “Why does this happen?” to uncover sub-causes

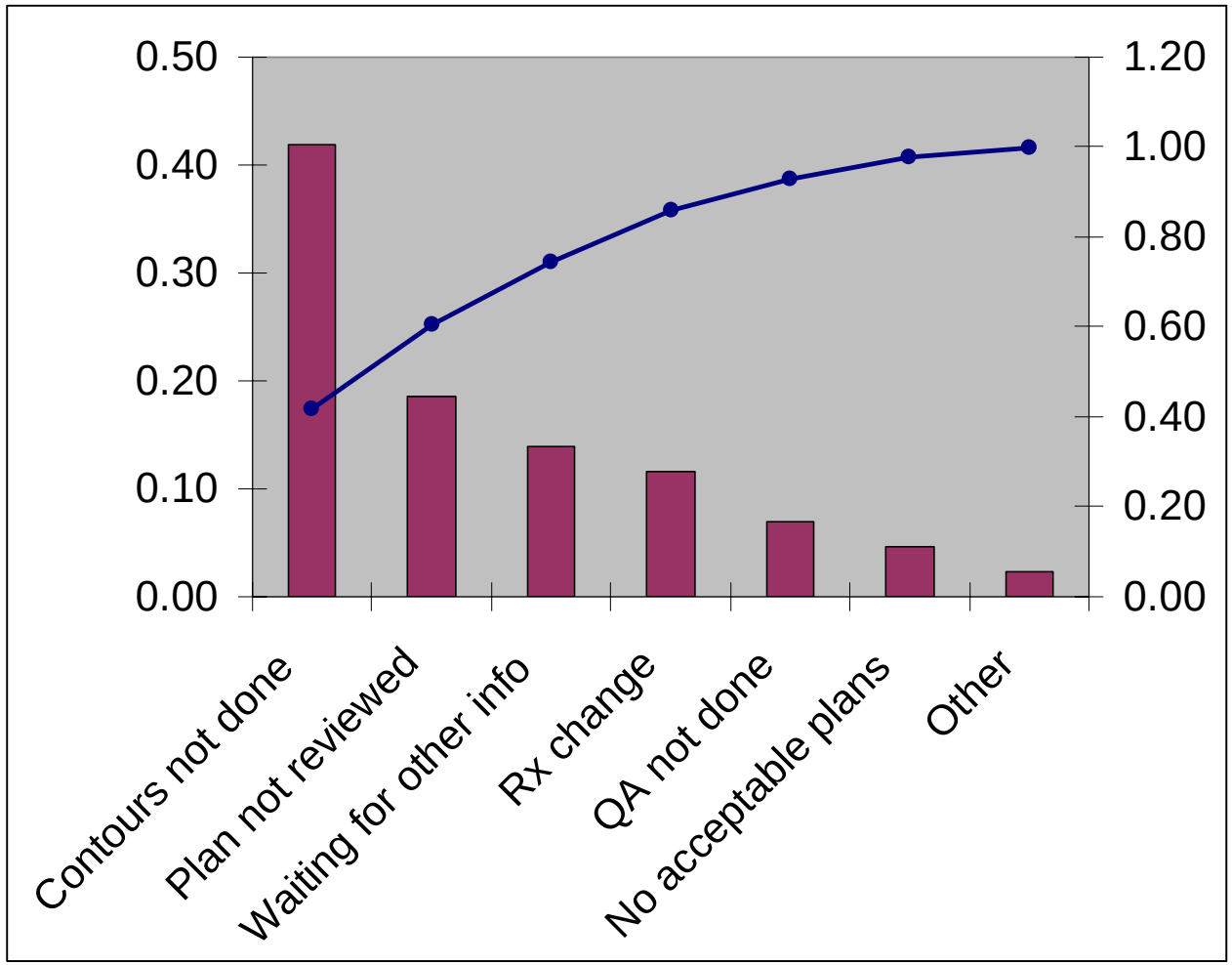
Cause-and-Effect Diagram



Pareto Chart

- When to use
  - To analyze the frequency of problems
  - To focus on the most significant problems
- General method
  - Decide on categories, measurements, and period of time
  - Subtotal the measurements for each category
  - Plot as a bar graph from largest to smallest

Pareto Chart



Root Cause Analysis (RCA)

- When to use
  - To identify what, how and why something has happened to prevent recurrence
- General method
  - Data collection
  - Causal factor charting
  - Root cause identification
  - Recommendation and implementation

Rooney and Vanden Heuvel. Root Cause Analysis for Beginners. Quality Progress. 2004:45-53.

Evaluation and Decision Making

- Decision matrix
  - Evaluates and prioritizes a list of options
  - Uses pre-determined weighted criteria
- Multi-voting
  - Narrows a large list of possibilities to a final selection
  - Allows an item that is favored by all, but not the top choice of any, to be selected

Decision Matrix

- When to use
  - A list of options must be narrowed to one
  - The decision is made on the basis of several criteria
- General method
  - Determine the evaluation criteria
  - Assign a relative weight to each criterion
  - Create a matrix that give a final highest weight to one criterion

Decision Matrix

		Possible Treatment Plans					
Criteria	Weight	3DCRT		IMRT 1		IMRT 2	
		Rating	Score	Rating	Score	Rating	Score
Target Coverage	**8**	9	72	10	80	8	64
Target Homogen	**2**	9	18	5	10	7	14
NT Sparing	**7**	1	7	9	63	9	63
Tx Time	**5**	9	45	4	20	5	25
Error Free	**3**	7	21	9	27	9	27
Decision			**163**		**200**		**193**

Process Analysis

- FMEA
  - Systematic method of analyzing and ranking the risks associated with various modes of failure
- Mistake-proofing
  - A method that either makes it impossible for an error to occur or makes the error immediately obvious once it occurs

Failure Modes & Effects Analysis

FMEA – TG100

- When to use
  - When a process or equipment is being applied in a new way
  - When a process or equipment is being designed or redesigned
  - When analyzing failures of an existing process or use of equipment
- General method
  - Please visit Medical Errors II
  - Wednesday, August 2. Rm 230A, 10-Noon.

Mistake-Proofing

- When to use
  - At a hand-off step in a process
  - When the consequences of an error are dangerous
- General method
  - Create flowchart of the process
  - Find source of each potential error
  - Elimination, Replacement, or Facilitation
  - Test it, then implement it (inspection)

Data Collection and Analysis

- Statistical Process Control (SPC)
  - Monitor and control variation in a process or product over time
  - Strikes a balance between two types of mistakes we can make in quality control
    - Looking for problems when they do not exist
    - Not looking for problems when the do

Process Control

- A definition of control
  - A process will be said to be predictable when, through the use of past experience, we can describe, at least within limits, how the process will behave in the future.

- SPC is concerned with practical methods to satisfy this definition

W.A. Shewhart. Economic Control of Quality of Manufactured Product. 1931:ASQ Quality Press Publications.

Process Control

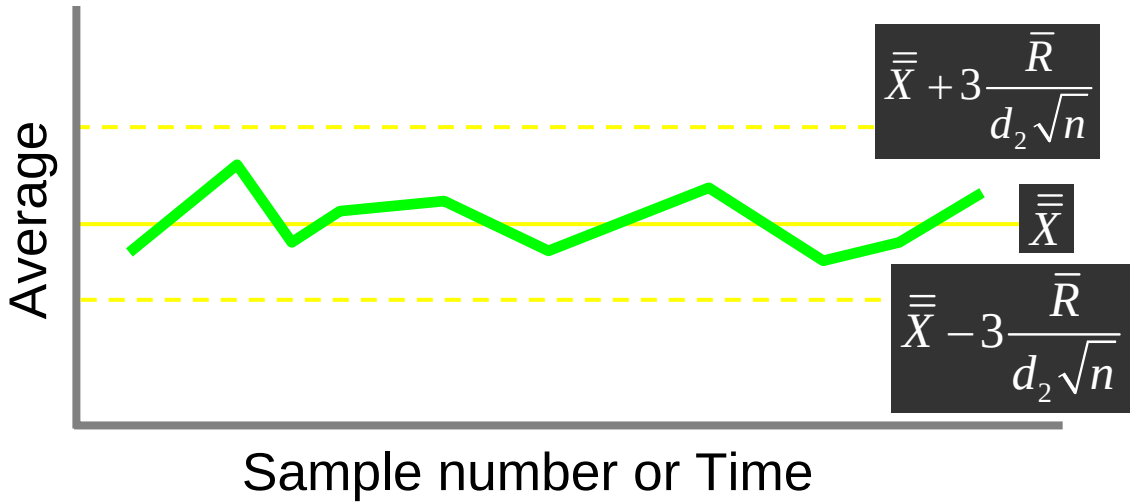
- Every measurable phenomenon or process displays variation
- There are 2 types of causes of variation
  - Exceptional variation
    - Assignable cause(s) exist and once removed will reduce variation
  - Routine variation
    - No readily assignable cause(s) exist

Process Control

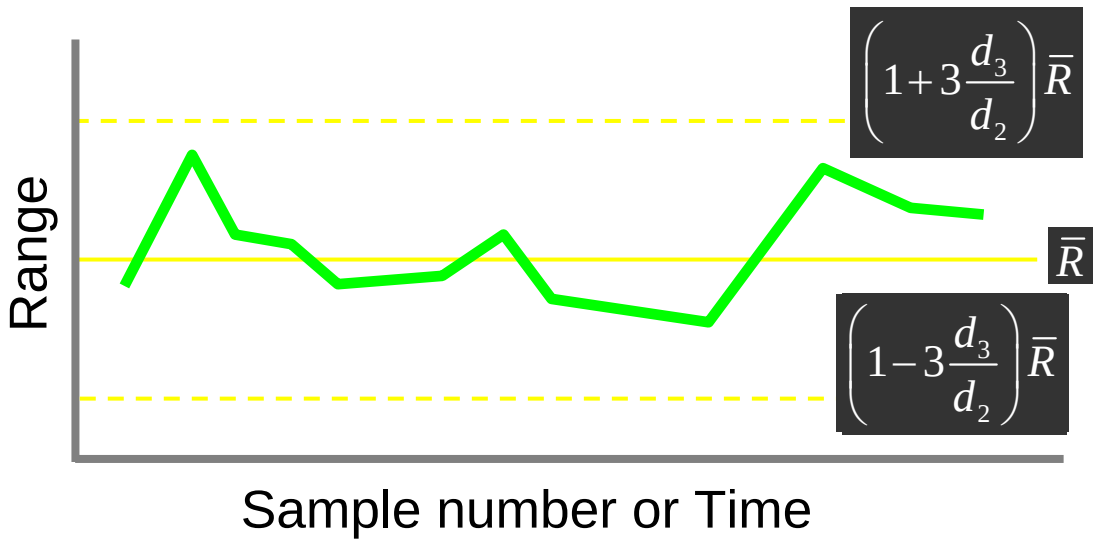
- Process behavior charts
  - Use a sequence of data for predictions of what will occur in the future
  - Subgroups from a time-ordered stream of data are used to describe process behavior
- A process is predictable when it is in a state of statistical control

Process Behavior Charts

One chart for the **subgroup mean**



One chart for the **subgroup range**



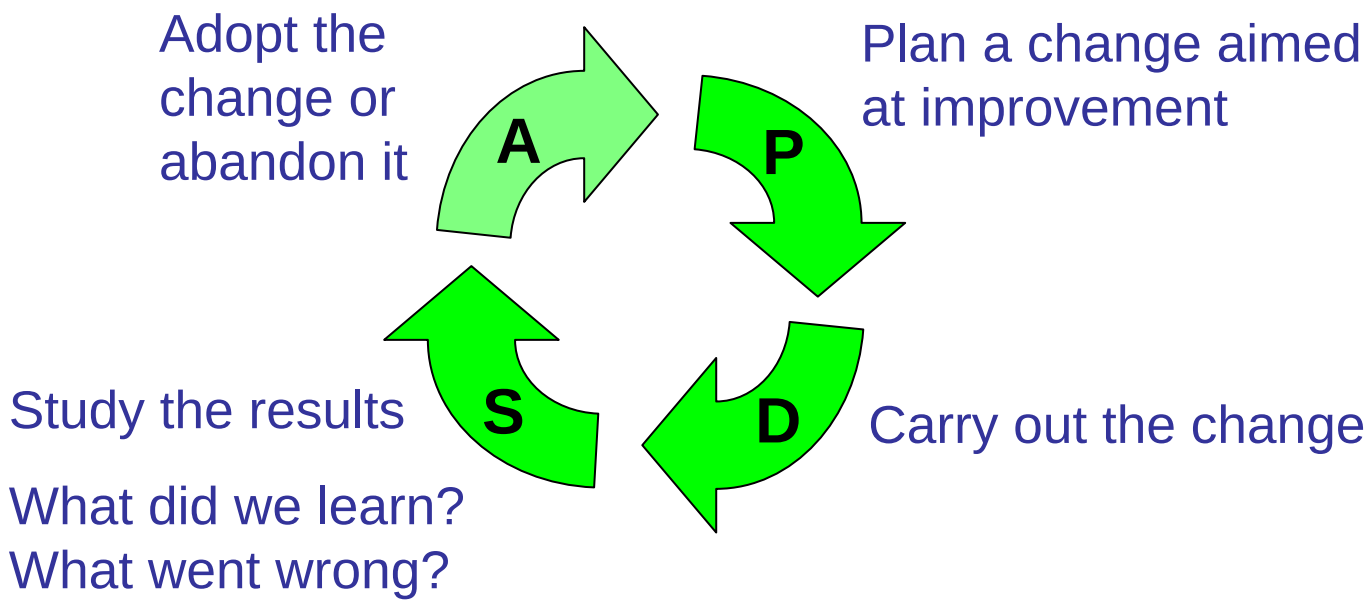
Project Planning/Implementation

- Models to carry out change and continued improvement
  - Plan-do-study-act (PDSA)
  - Define, Measure, Analyze, Improve and Control (DMAIC)

- Design for Six-sigma (DFSS)
  - Answers the question, “How much risk is in my design?”

PDSA

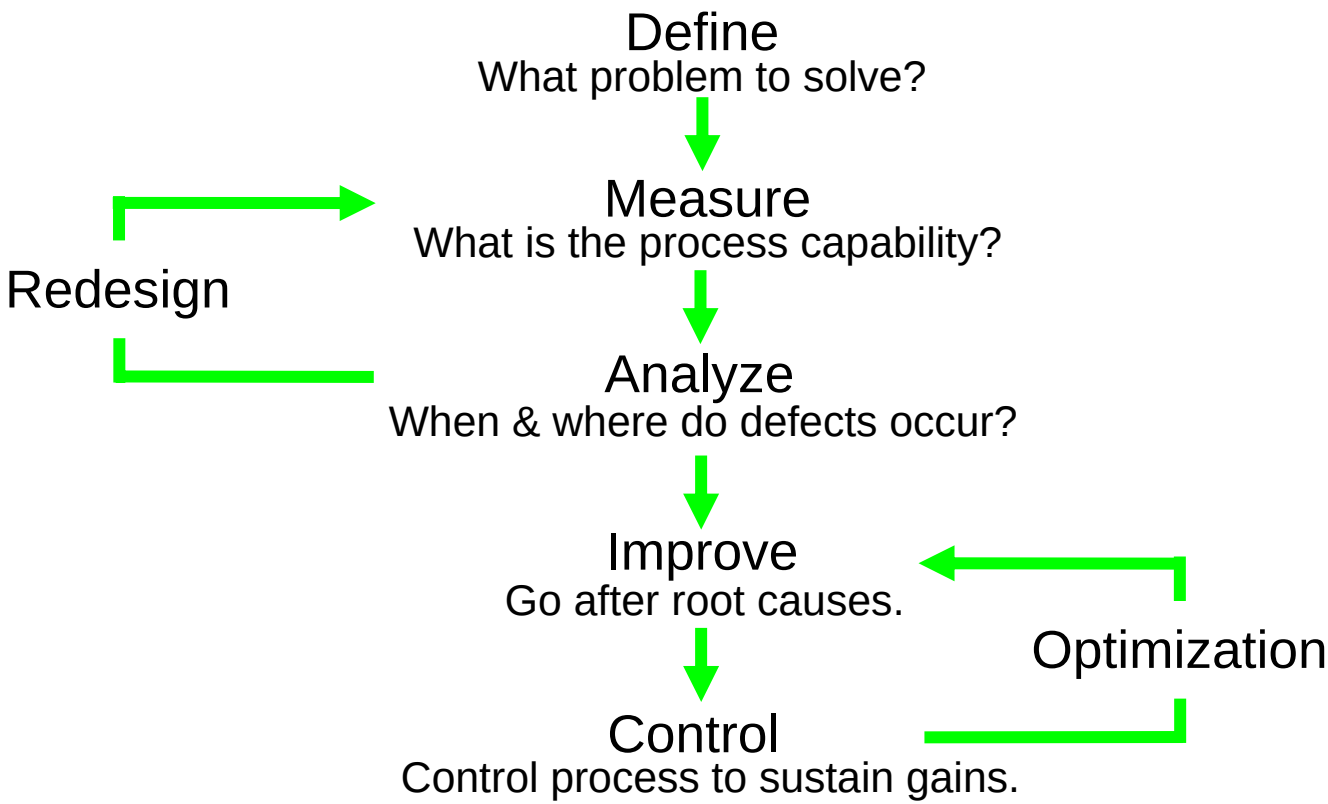
- Plan – Do – Study – Act
- Shewhart cycle for learning and improvement



E Deming. The New Economics. 1993: MIT, Center for Advanced Engineering Study. Figure 13.

DMAIC

- Define – Measure – Analyze – Improve – Control
- Data-driven strategy for improving processes



Design for Six-Sigma (DFSS)

- A process of predicting response variation
  - Calculate variance due to specific noise
- Can answer the question; How much risk is in my design?
- Methods include
  - Deterministic
  - Stochastic

Philosophy Paradigms

- Six-Sigma
  - Disciplined methodology of improving products and processes
- Lean
  - Processes are continually evaluated for waste
- Total Quality Management (TQM), Business Process Reengineering (BPR), etc…

What Have We Omitted

$C_{p,k}$

PDPC

Hypothesis Testing

Gage R&R

Tree Diagram

C_p

Fault Tree Analysis

Situational Awareness

Check Sheet

Scatter Diagram

Relations Diagram

Gnatt Chart

Brainstorming

Matrix Diagram

Arrow Diagram

Stratification

Survey

DCOV

Histograms

Benchmarking

List Reduction

Summary

- Quality/error reduction innovations may not seem technologically significant but are extremely important for our patients

- Increased efforts should be aimed at reducing errors and chronic sources of defects from clinical processes

Summary

- Our best efforts are not good enough
  - We can’t do everything we think of
  - We have to assess risk and choose our focus carefully (TG100!)
- Quantitative quality control techniques require training and practice
- Leadership must make quality a priority (AAPM / ASTRO)

Proposals for AAPM

- Physicists should champion error reduction and quality control
- Future AAPM meetings should have a specific research session for error/cost reduction and quality control
- Create a working group/task group charged to understand and describe the vast amount of quality techniques

Some Further Reading

- W.E. Deming. **On Probability as a Basis for Action**. The American Statistician, 29(4):146-52, 1975.
- **Six part series on Quality of Health Care**. The New England Journal of Medicine, 335(12-17), 1996.
- S.J. Goetsch. **Risk Analysis of Leksell Gamma Knife Model C with Automatic Positioning System**. IJROBP, 53(2):869-77, 2002.
- Patton et al. **Facilitation of Radiotherapeutic Error by Computerized Record and Verify Systems**. IJROBP, 56(1):50-7, 2003.
- Thomadsen et al. **Analysis of Treatment Delivery Errors in Brachytherapy Using Formal Risk Analysis Techniques**. IJROBP, 57(5):1492-508, 2003.
- Dixon and O'Sullivan. **Radiotherapy Quality Assurance: Time for Everyone to Take It Seriously**. European Journal of Cancer, 39:423-9, 2003.
- Pawlicki et al. **Statistical Process Control for Radiotherapy Quality Assurance**. Med Phys, 32(9):2777-86, 2005.
- Van Tilburg et al. **Health Care Failure Mode and Effect Analysis: A Useful Proactive Risk Analysis In A Pediatric Oncology Ward**. Quality and Safety in Health Care, 15:58-64, 2006.