Six Sigma and Risk Management in Health Care

Professor Ron Kenett

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משרד הבריאות

Israel Medical Association First Workshop on Safety in Patient Care

Ashkelon, 6/9/2007

INBAL INSURANCE COMPANY LTD. ענבל חברה לביטוח בע"מ

Agenda

- **Six Sigma** basics (The Juran Trilogy, DMAIC)
- Useful tools (Flow charts, Pareto charts, control charts)
- IHI
- SSM example
- **Risk Management**
- Risk Management examples

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Who implements Six Sigma ?

Abbott Labs, Adolph Coors, Advanced Micro Devices, Aerospace Corp, Alcoa, Allen Bradley, Allied Signal, Ampex, Apple Computers, Applied Magnetics, Atmel, Baxter Pharmaseal, Beatrice Foods, Bell Helicopter, Boeing, Bombardier, Borden, Bristol Meyers - Squibb, Bryn Mawr Hospital, Campbell Soup, Cellular 1, Chevron, Citicorp, Clorox, Cooper Ind, Dannon, Delnosa, Digital Equipment Corp, DTM Corp, Eastman Kodak, Electronic Systems Center, Empak, Florida Dept. of Corrections, Ford Motor Company, GEC Marconi, General Dynamics, General Electric, Glaxo Smith Kline, Hazeltine Corp, Hewlett packard, Holly Sugar, Honeywell, Intel, Junior Achievement, Kaiser Aluminum, Kraft General Foods, Larson & Darby, Inc, Laser Magnetic Storage, Lear Astronics, Lenox China, Littton Data Systems, Lockheed Martin, Loral, Los Alamos National labs, Martin Marietta, McDonnell Douglas, Merix, Microsoft, Morton Int'l, **Motorola**, NASA, Nat'l Institute of Corrections, Nat'l Institute of Standards, Nat'l Semiconductor, Natural Gas Pipeline Company of America, NovoNordisk Northrop Corp, PACE, Parkview Hospital, Pentagon, Perrigo, Pharmacia, PRC, Inc, Qualified Specialists, Ramtron Corp, Rockwell Int'l, Rohm & Haas, Seagate, Society of Plastics Engineers, Serono, Solar Optical, Sony, Star Quality, Storgae Tek, Symbios Logic, Synthes, Technicomp, Tessco, Texaco, Texas Commerce Bank, Texas Dept. of Transportation, Texas Instruments, Titleist, Trane, TRW, Ultratech Stepper,United technologies, UPS, USAA, Verbatim, Walbro Automotive, Walker parking, Woodward Governor, Xerox,

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Why Six Sigma?

"At Motorola we use statistical methods daily throughout all of our disciplines **to synthesize an abundance of data to derive concrete actions**….

How has the use of statistical methods within Motorola Six Sigma initiative, across disciplines, contributed to our growth? Over the past decade **we have reduced in-process defects by over 300 fold**, which has resulted in a cumulative manufacturing **cost savings of over 11 billion dollars**"*.

Robert W. Galvin
Chairman of the Executive Committee
Motorola, Inc.

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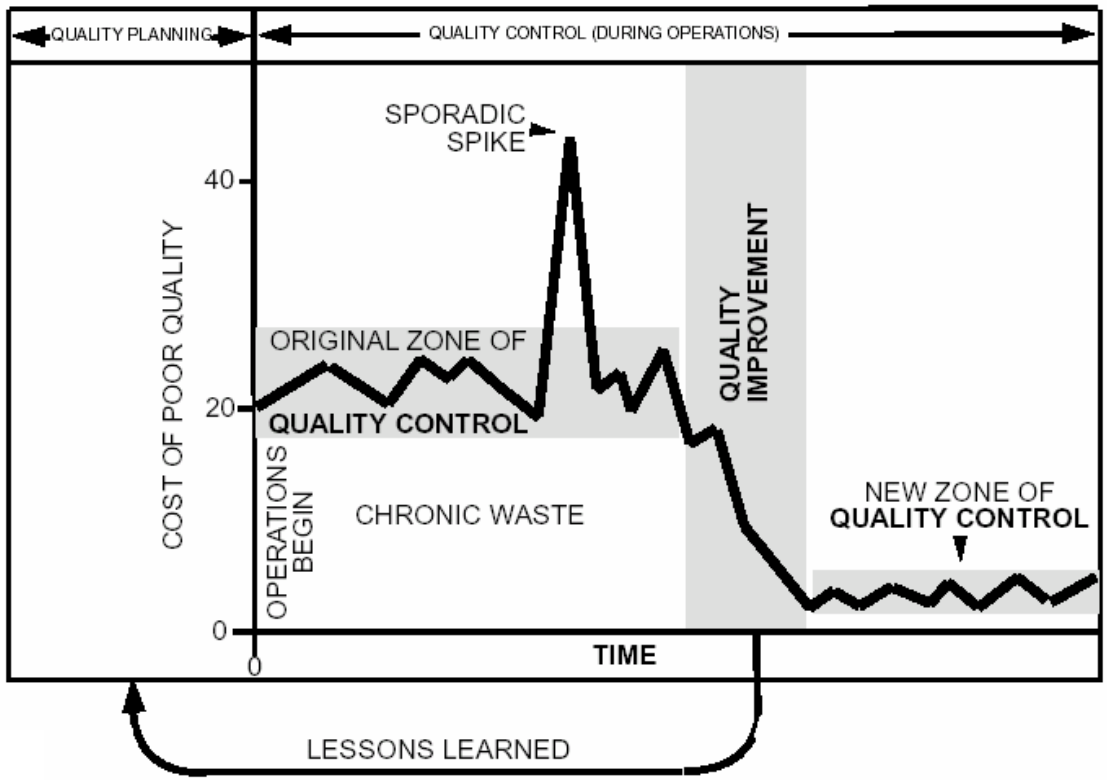
***From the forward to MODERN INDUSTRIAL STATISTICS by Kenett and Zacks, Duxbury, 1998**

The Juran Trilogy: Planning, Improvement and Control*



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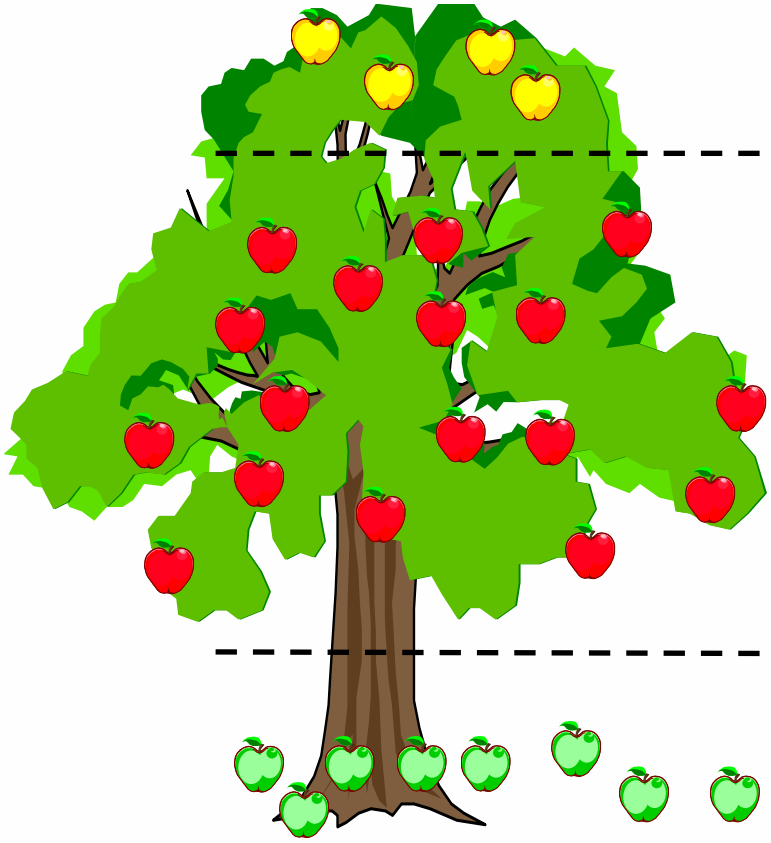
*J.M. Juran, Juran on Leadership for Quality, Free Press, 1989

Six Sigma projects



Degree of Difficulty

Sweet Fruit
(Quality by Design Projects)

Bulk of Fruit
(Process Characterization
and Optimization Projects)

Six Sigma Projects

Low Hanging Fruit
(Seven Basic Tools Projects)

Ground Fruit
(Logical Projects)

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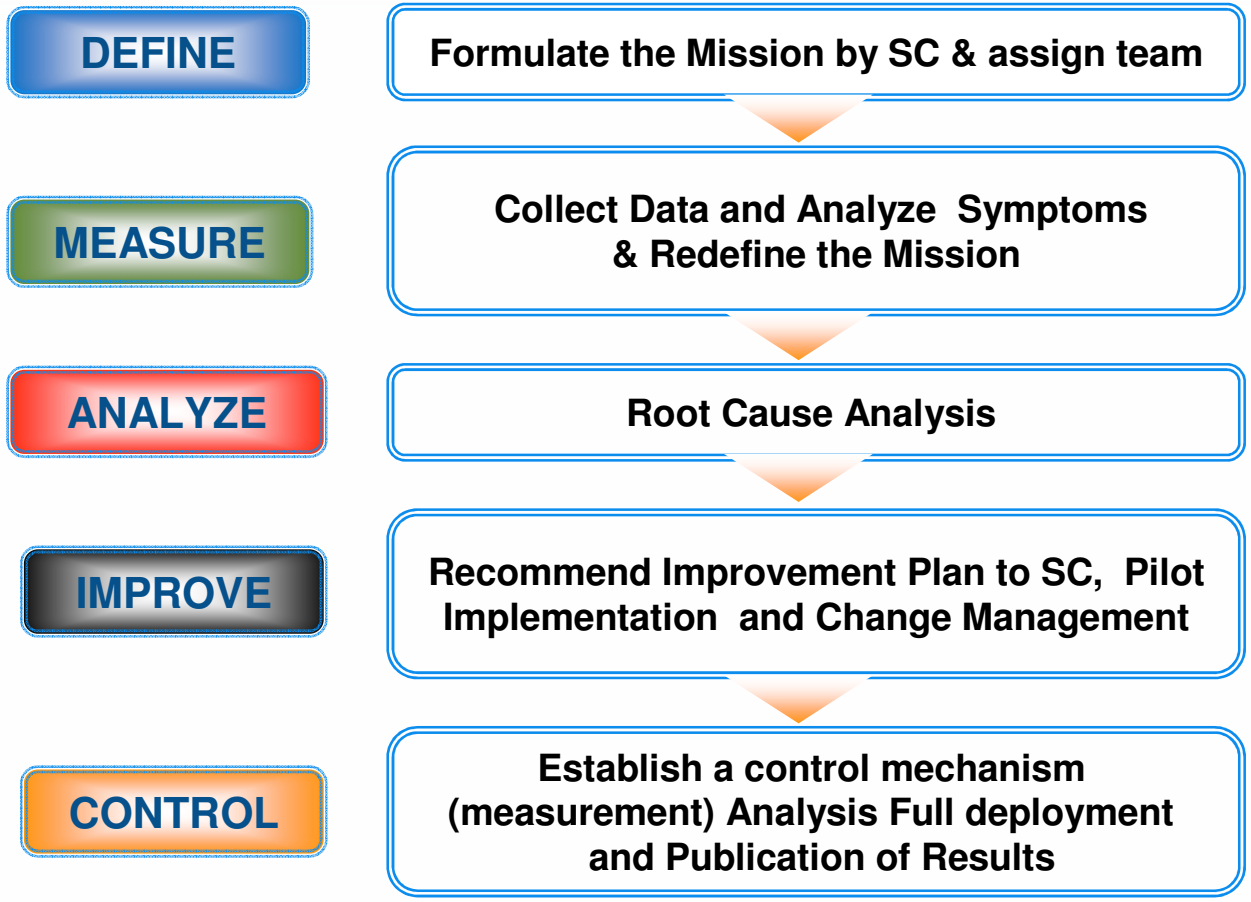
Six Sigma methodology: DMAIC



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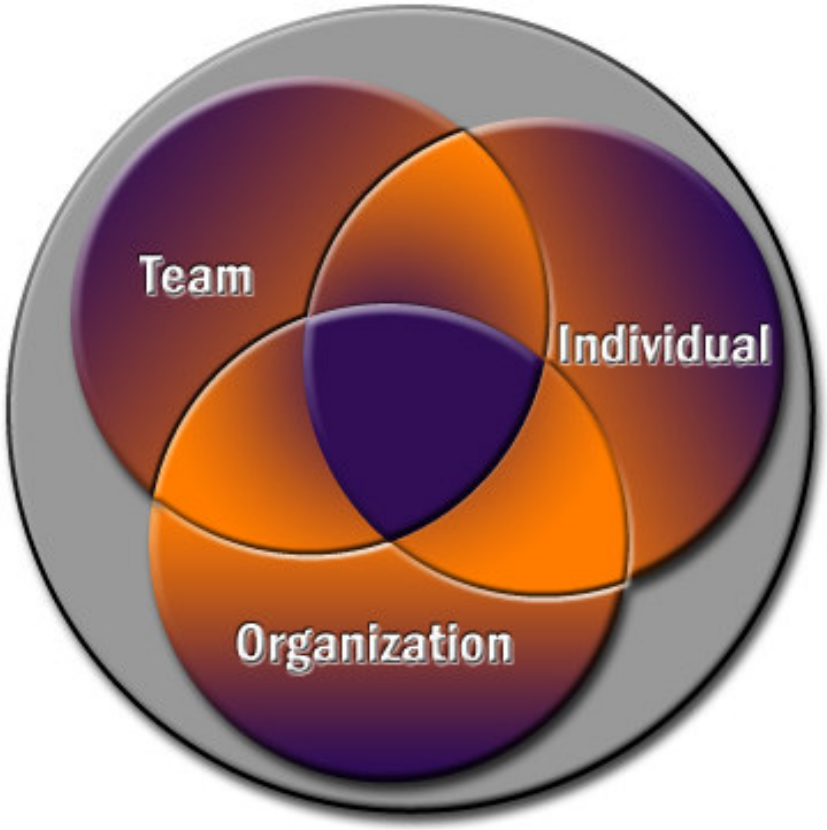
SC: Steering Committee

Three levels of competence



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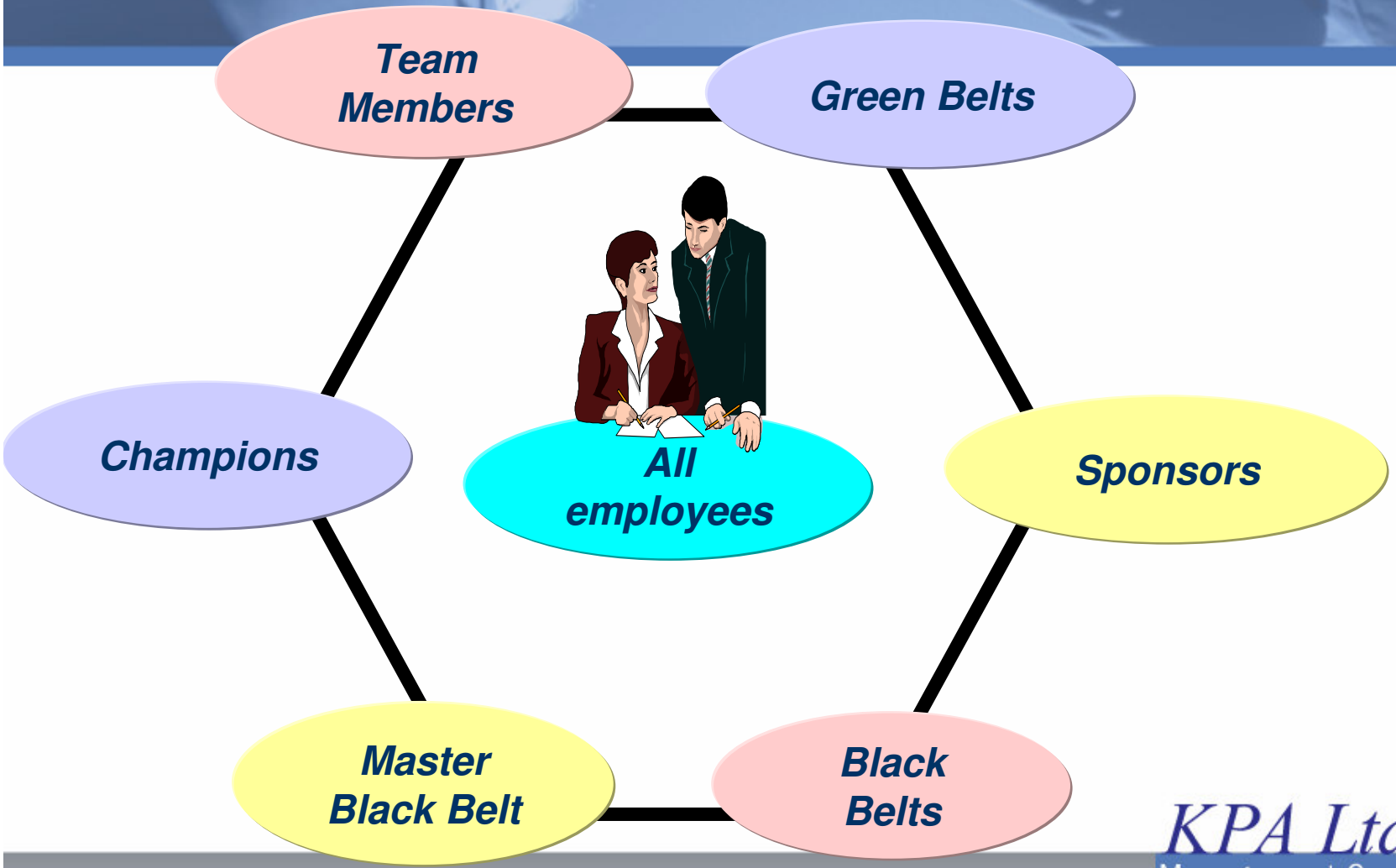
Six Sigma Key Players



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Six Sigma Key Players

Black Belts

Quality & Industrial Engineers

Statisticians

Technical Skills

Quality Improvement Facilitators

Soft Skills

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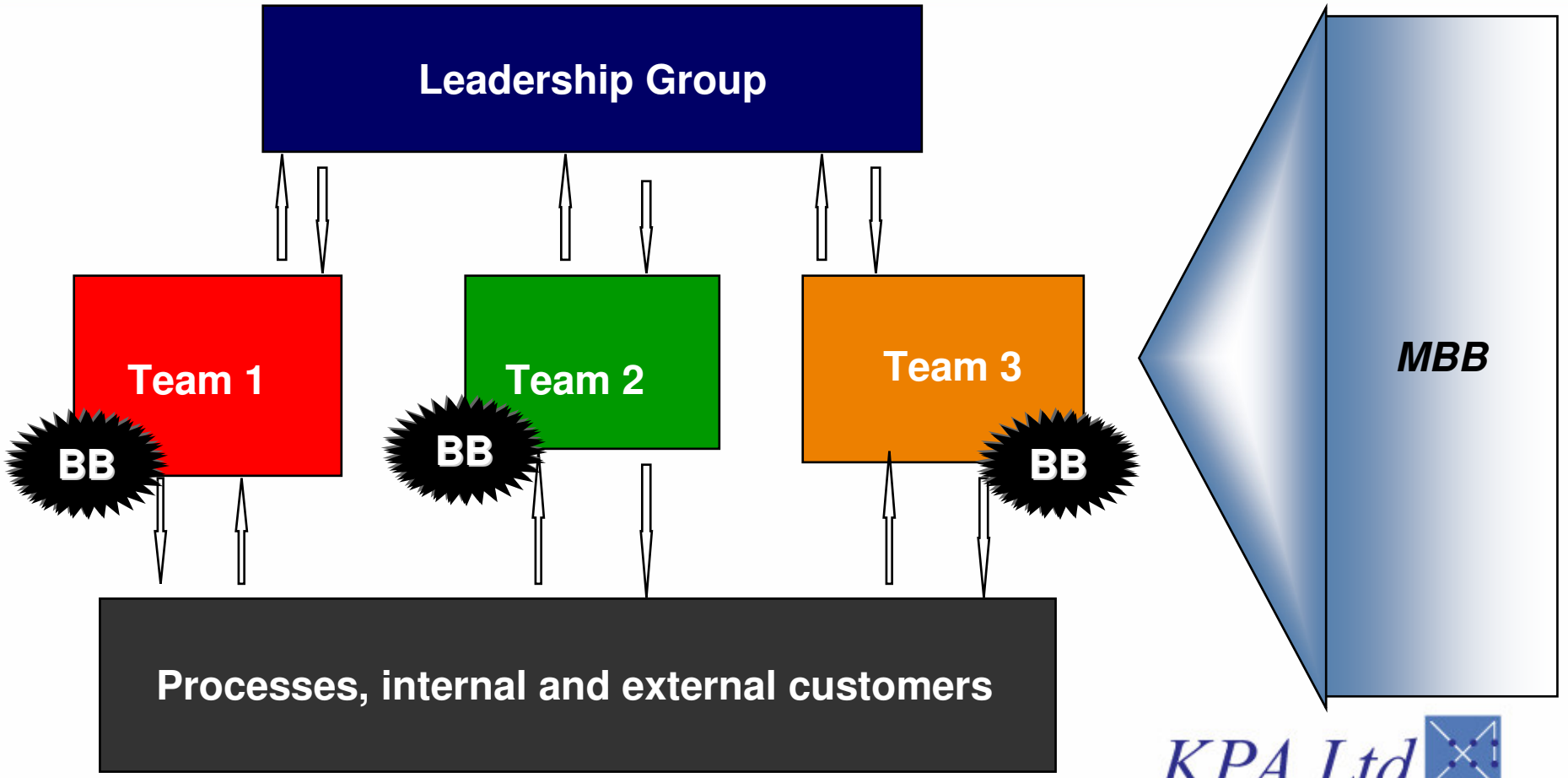
Six Sigma Organizational Structure



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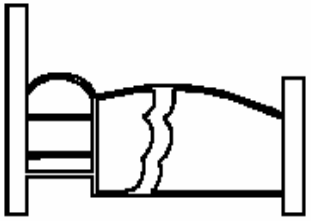
An example

Medicine

Surgery

Nursing

Catheter



Bed

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US statistics

Report Finds Drug Errors Hurt 1.5 Million a Year

AFX.COM

July 21, 2006

More than 1.5 million Americans are injured every year by drug errors in hospitals, nursing homes and doctor's offices, a count that doesn't even estimate patients' own medication mix-ups, says a report that calls for major steps to increase patient safety.

Topping that list: All prescriptions should be written electronically by 2010, the Institute of Medicine said. At least a quarter of all medication-related injuries are preventable, the institute concluded in the report it released Thursday.

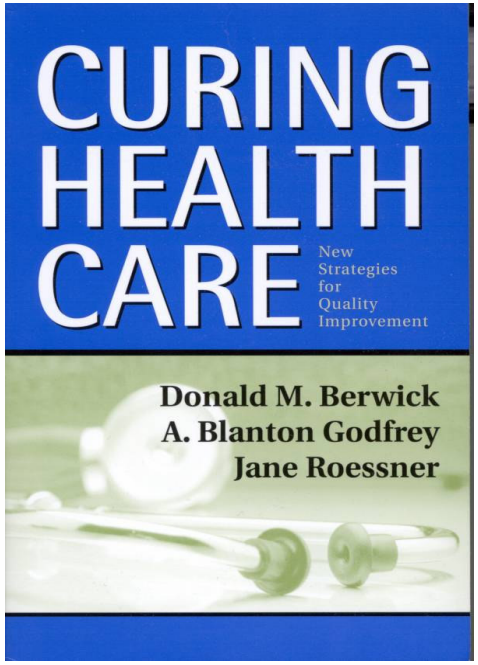
Perhaps the most stunning finding of the report was that, on average, a hospitalized patient is subject to at least one medication error per day, despite intense efforts to improve hospital care in the six years since the institute began focusing attention on medical mistakes of all kinds.

The new probe couldn't say how many victims of drug errors die. A 1999 estimate put the number of deaths, conservatively, at 7,000 a year. Also unknown is how many of the injuries are serious.

But a preventable drug error can add more than $5,800 to the hospital bill of a single patient. Assuming that hospitals commit 400,000 preventable drug errors each year, that's $3.5 billion□not counting lost productivity and other costs□from hospitals alone, the report concluded.

The Institute for Healthcare Improvement

- National Demonstration Project for Improving the Quality of Healthcare (1987)
- Expansion of project to become IHI
- Impact on healthcare in the U.S. and the world.
- Over 2,200 hospitals enrolled in all 50 states (Nearly 50% of U.S. hospital beds)
- Results and examples available on **www.ihi.org**



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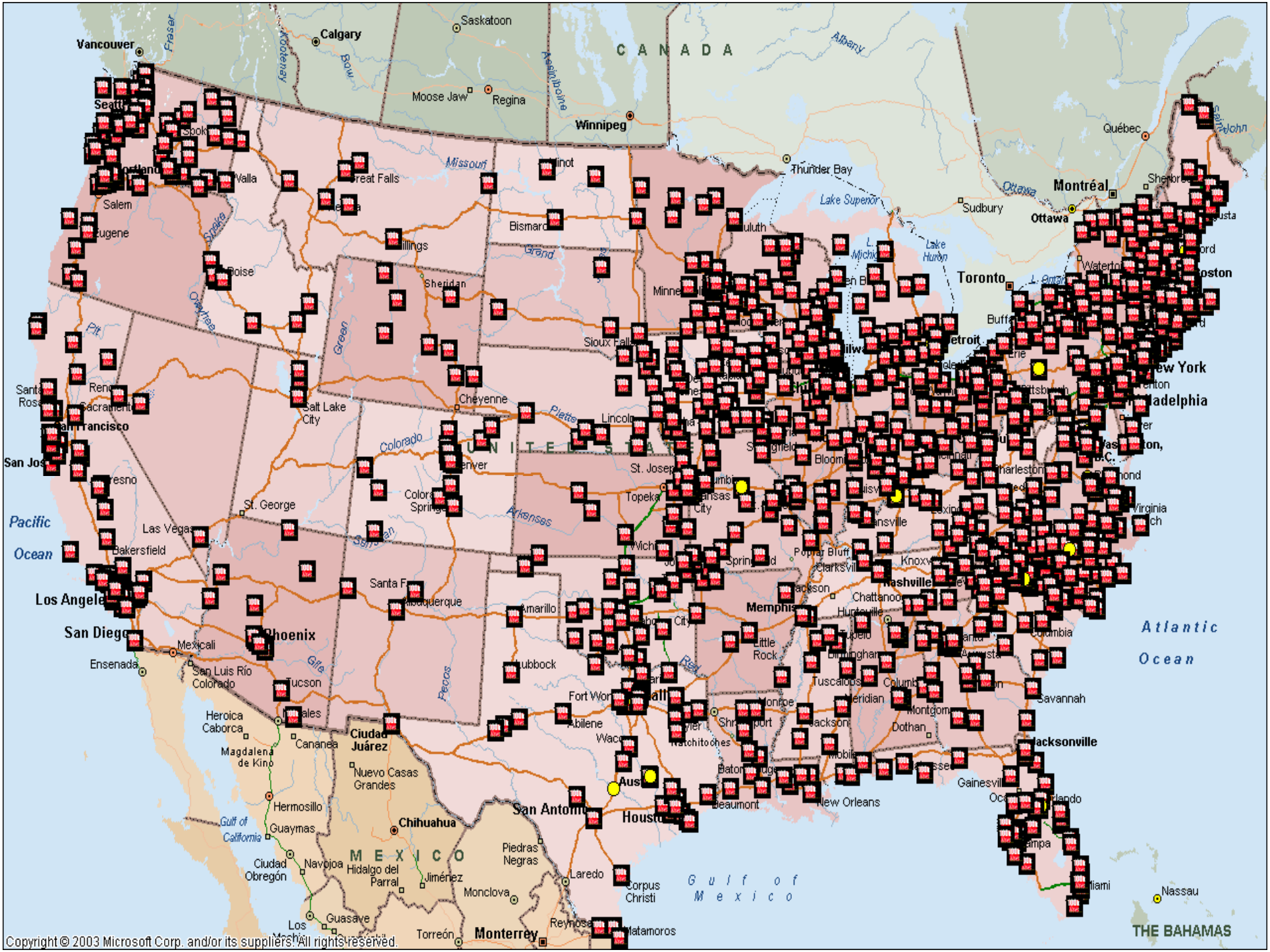

Some is not a number… soon is not a time

122,000 lives were saved

The Number:

100,000 Lives

The Time:

June 14, 2006 – 9 a.m. ET

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New goal: 5 million fewer patients injured (not just killed)

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Six changes that save lives (from IHI)

- Deploy Rapid Response Teams
- Deliver Reliable, Evidence-Based Care for Acute Myocardial Infarction (Heart Attacks)
- Prevent Adverse Drug Events (ADEs)
- Prevent Central Line Infections
- Prevent Surgical Site Infections
- Prevent Ventilator-Associated Pneumonia

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Examples of health care variables

- Lab turnaround time
- Days from positive mammogram to definitive biopsy
- Patient satisfaction scores
- Medication error counts
- Emergency service response times
- Infection rates
- Mortality rates
- Number of patient falls
- Post-operative length of stay
- "Door-to-needle" time ……and many others…

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Six Sigma goals

Sigma	Defects Per Million
1	690,000
2	308,000
(90% OK	100,000)
3	66,800
(99% OK	10,000)
4	6,210
5	230
6	3.4

Airline deaths ⇨

- **> 6 Sigma = .000043% = 0.43 deaths per million passenger boardings**

Airline baggage handling ⇨

- **~ 4 Sigma = 0.6 % = ~ 6,000 lost bags per million checked**

ER missed diagnosis of Acute Myocardial Infarction* ⇨

- **2 - 4 Sigma = 2% - 8% = 20,000 - 80,000 missed diagnoses per million AMIs**

*** NEJM, Vol 342, No 16**

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The useful ten

- **Location Plots**
- **Pareto Charts**
- **Control Charts**
- Flowcharts
- Checksheets
- Histograms
- Ishikawa Diagrams (Cause-and-Effect Diagrams)
- Scatterplots
- Boxplots
- Bars, Stars, and Pies

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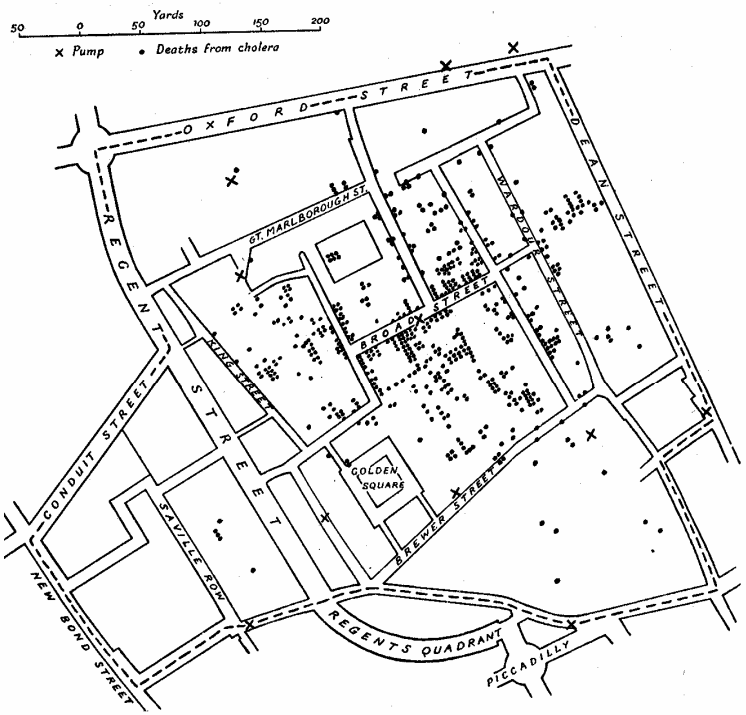
Location plots



- From NEJM: The origin of modern epidemiology:
- 1854, when John Snow demonstrated the transmission of cholera from contaminated water
- The majority of people who got ill used the Broad Street Pump in London's Golden Square
- He removed the pump handle from the polluted well and the spread of the disease stopped.

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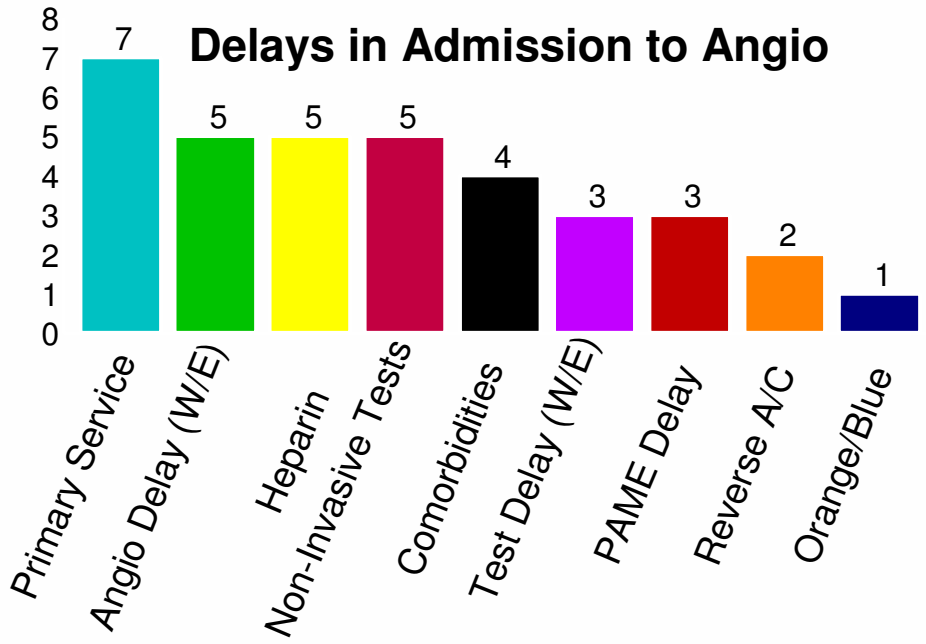
Pareto charts



"…a man who has carefully investigated a printed table, finds, when done, that he has only a very faint and partial idea of what he has read; and that like a figure imprinted on sand, is soon totally erased and defaced."

William Playfair (1786), *The Commercial and Political Atlas*

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SSM HEALTH · CARE

"Through our exceptional health care services, we reveal the healing presence of God."

SSM Health Care — Leading the Way

Founded more than 130 years ago by Mother Mary Odilia Berger and sponsored today by the Franciscan Sisters of Mary

SSM Health Care is a private, not-for-profit health care system based in St. Louis, Mo, that provides primary, secondary, and tertiary health care services.

The system owns, manages, and is affiliated with 21 acute care hospitals and three nursing homes in four states: Illinois, Missouri, Oklahoma, and Wisconsin.

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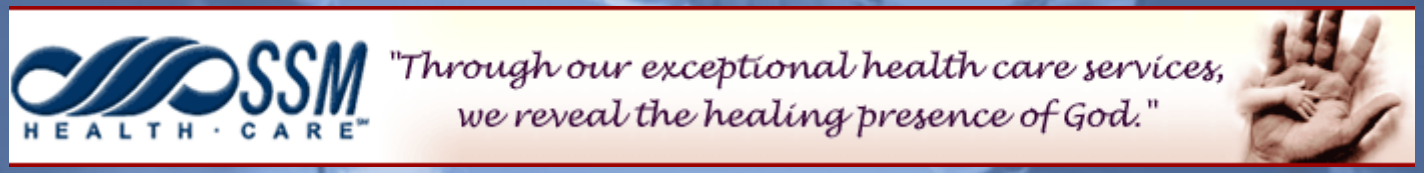

• In 1999, SSMHC started a clinical collaborative program with 4 teams to improve patient outcomes. By 2002, 85 teams have been involved in six clinical collaboratives.

• Physicians connected to an automated information system have increased steadily from 3,200 in 1999 to 7,288 in 2002.

• For four consecutive years, SSMHC has maintained an investment "AA Credit Rating"—a rating attained by fewer than 1 percent of U.S. hospitals.

• SSMHC's share of the St. Louis market increased over each of the past three years to 18 percent, while three of its five competitors lost market share.

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"Through our exceptional health care services, we reveal the healing presence of God."

SSM Health Care — Improvement Projects

- Safely Reducing Cesarean Sections
- Improving Outcomes and Reducing Costs in Adult intensive Care
- Improving Outcomes and Reducing Costs for Adult Cardiac Surgery
- Reducing Medication Errors
- **Reducing Radiology Retakes**
- Idealized Design of Clinical Office Practices
- Care at the End of Life
- Improving Secondary Prevention of Ischemic Heart Disease
- Using Patient Information to Improve Care and Ensure Success
- Decreasing Readmissions for Patients with Congestive Heart Failure
- Achieving Exceptional Safety in Health Care

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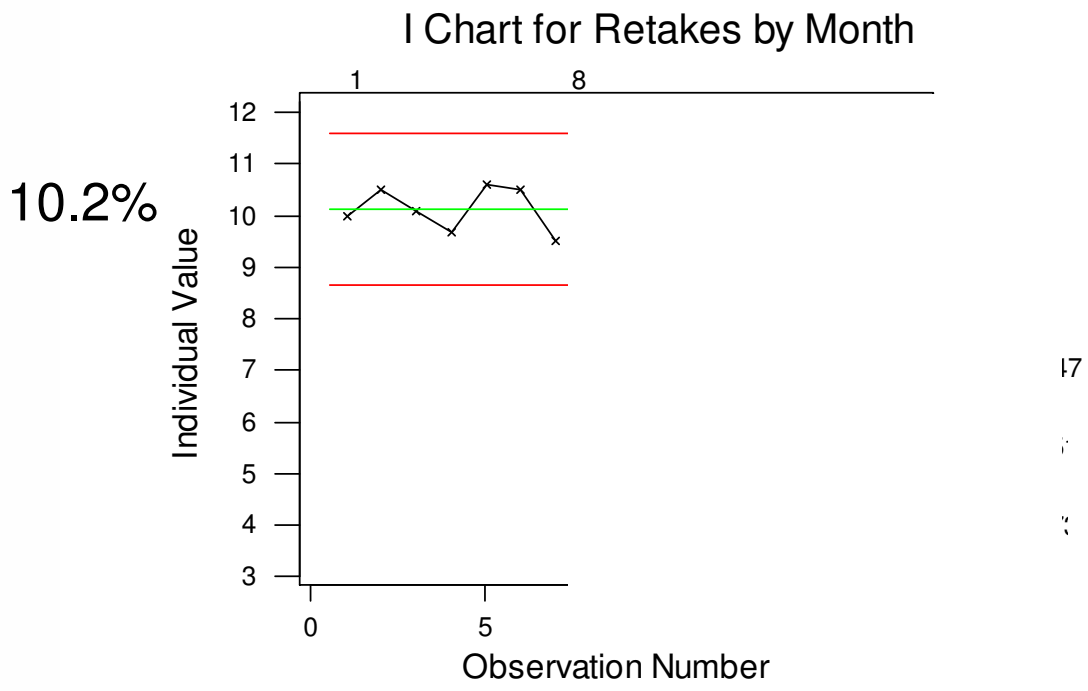
Radiology Retakes



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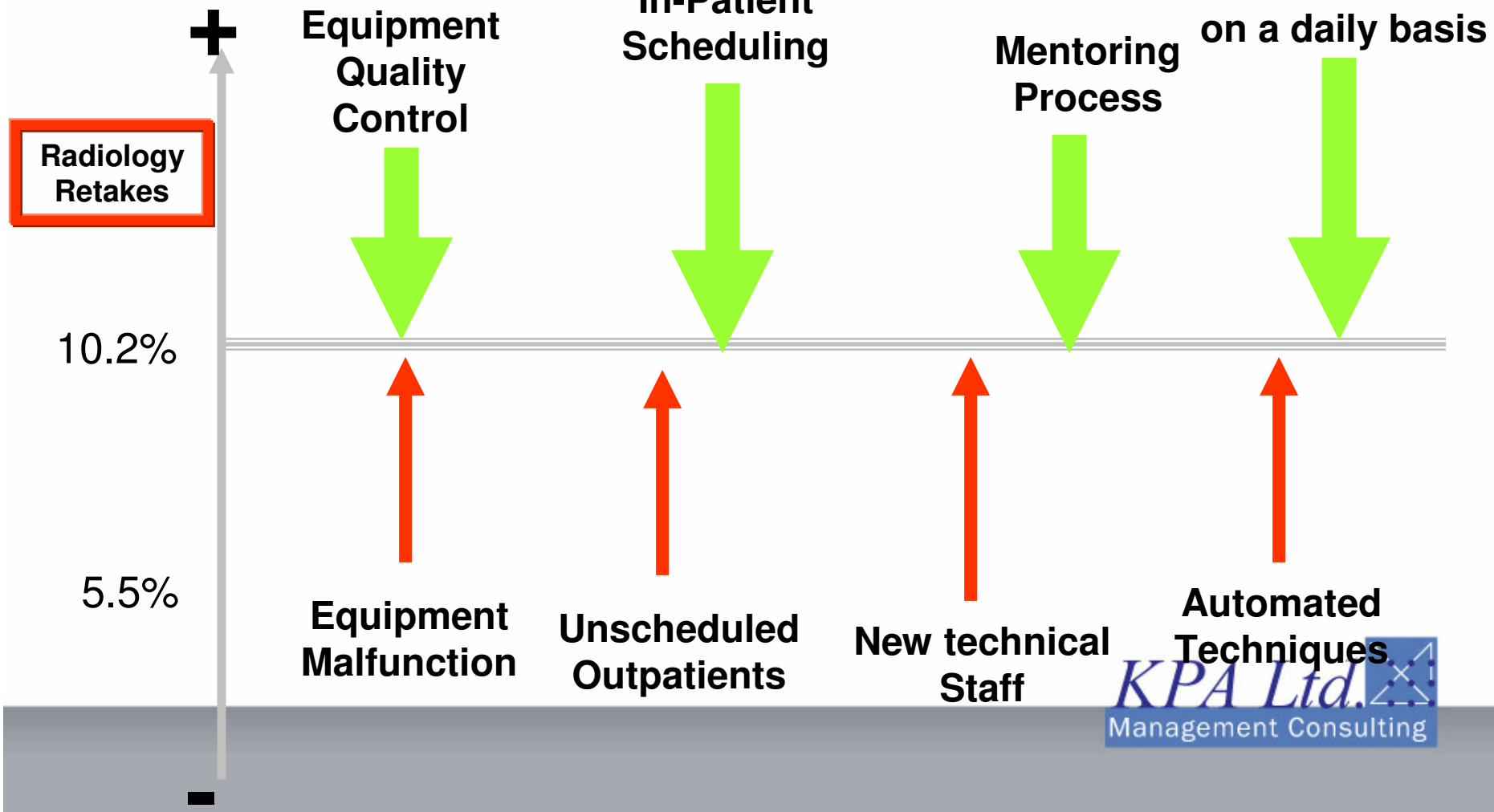

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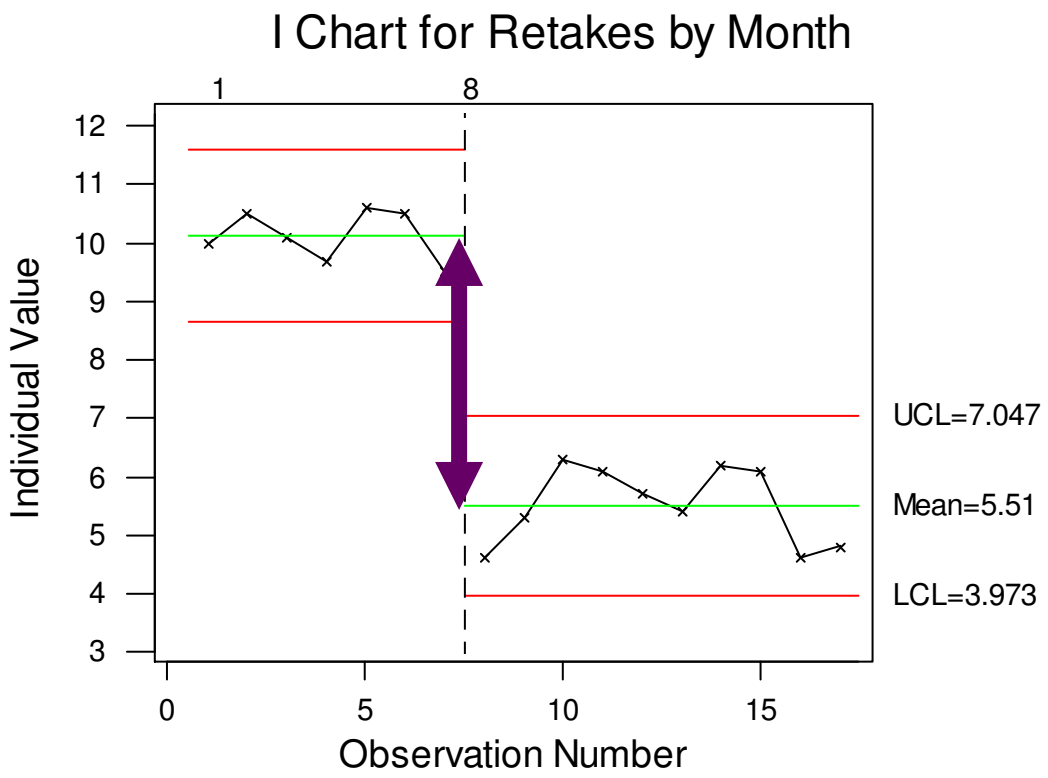
Radiology Retakes

10.2%

5.5%



What did we cover so far

- Six Sigma basics
  - What, Who, Why
  - The Juran Trilogy
  - The DMAIC process
- Useful tools
- IHI achievements at the national level
- SSM example

Risk Management in

R&D

Production

Testing

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Risk Management Methodology

Considers the type of risk and its effect on the person or organization

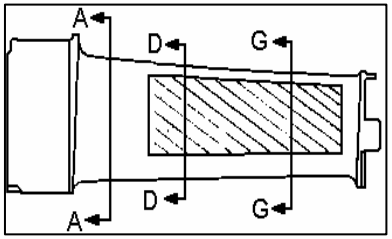
Is concerned with the attitude of the decision maker and the effects that this can have on the assessment of risk

Isolates the source and type of risk

Considers how the risk should be managed

Evaluates the consequences and likelihood of risk using analytical techniques.

Risk Management Methodology - Metalwork



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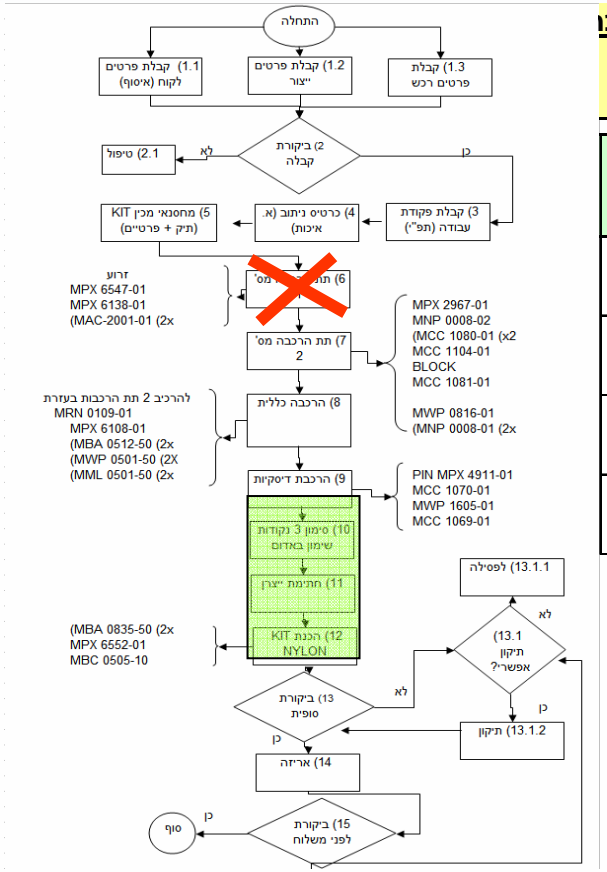
Production

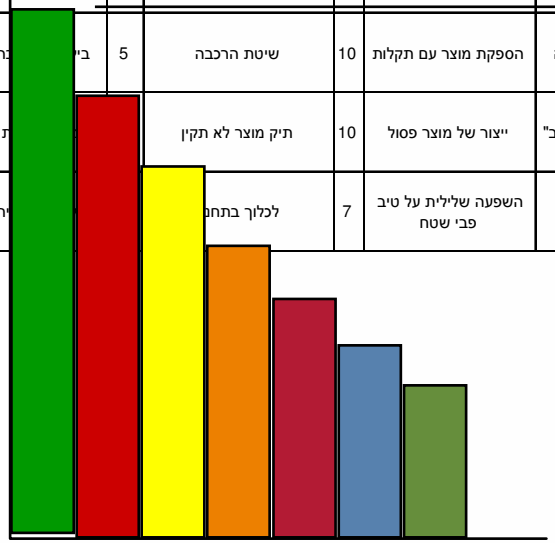
Risk Management Methodology - Metalwork FMEA



Severity Rating X **Occurrence Rating** X **Detection Rating** = **Risk Priority Number**

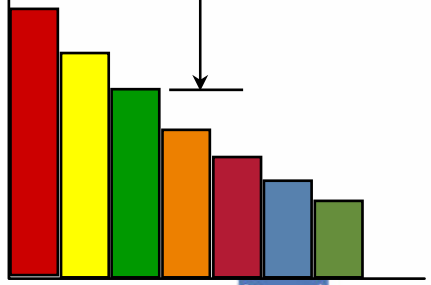
1	KIT NYLON	תהליך	הרכבה של המוצר בלי KIT	10	מוצר לא שלם	4	קיט לא מחובר לפריס	10	400
2	שיטת הרכבה	תהליך	אי גילוי תקלות / הרכבה לא יעילה	10	הספקת מוצר עם תקלות	5	שיטת הרכבה	6	300
3	קבלת הזמנה	INPUT	שינוי ב REV בלי בדיקה ב"המשבב"	10	ייצור של מוצר פסול	7	תיק מוצר לא תקין	9	270
4	ניקיון תחנת הרכבה	תנאי סביבה	תחנת הרכבה לא נקיה	7	השפעה שלילית על טיב פבי שטח	7	לכלוך בתחנ	7	245

Before



After

Improvement



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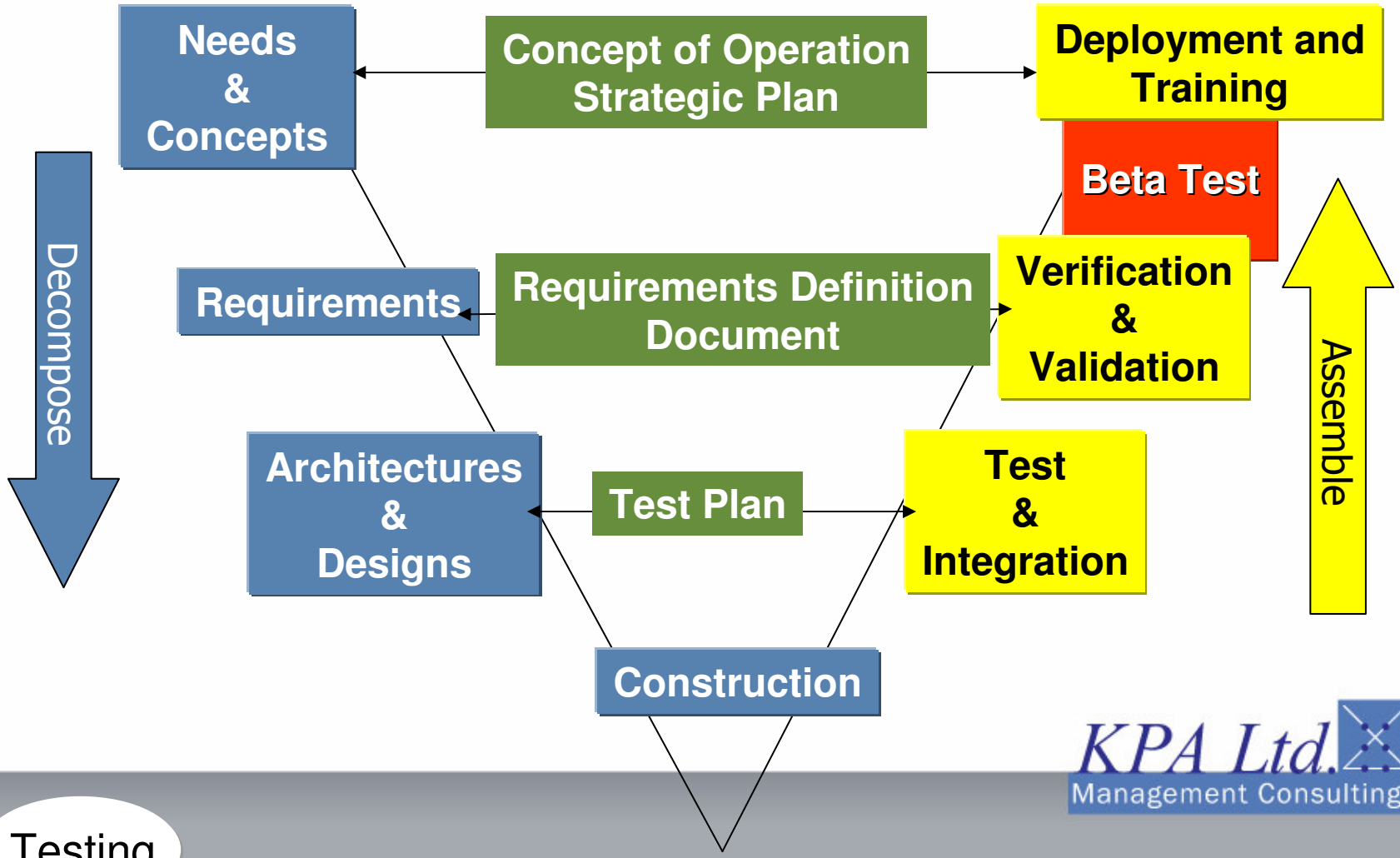
Production

Risk Management Methodology - Beta testing



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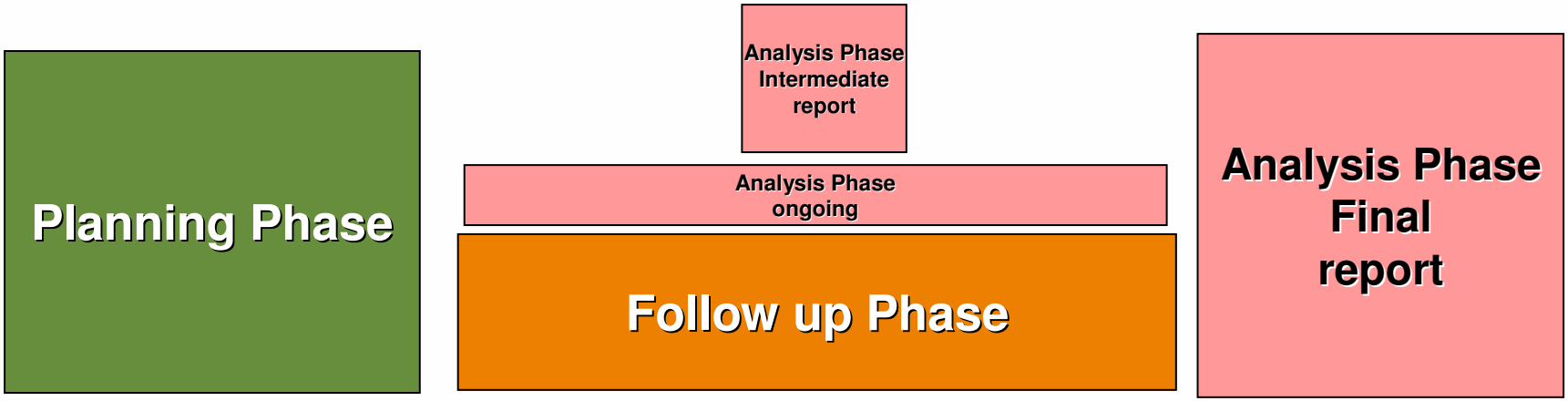
Testing

Risk Management Methodology - Beta testing



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Testing

Risk Management Methodology - Beta testing

	Schedule Impact		Cost Impact		Technical Impact	
RATING	SLIP PROBABILITY	AMOUNT	PROBABILITY	AMOUNT	ALTERNATIVES	PERFORMANCE
0.9	Certain, program threatening.	> 8 months	Certain, program threatening.	>9%	Cannot achieve.	Unacceptable.
0.8	Extensive, program threatening.	> 7 months	Extensive, program threatening.	>8%	Redesign or alternate reqd to achieve.	Inadequate.
0.7	Probable program threat.	> 6 months	Probable program threat.	>7%	No adequate backup.	Significantly degraded.
0.6	Possible program threat.	> 5 months	Possible prog. threat.	>6%	Inferior backup.	Degraded.
0.5	Potential program threat.	> 4 months	Within uncertainty range.	>5%	Several adequate alternatives.	Reduced.
0.4	Serious subsystem slip with alternatives.	> 3 months	Well within acceptable range.	>4%	Several adequate alternatives.	Slight reduction.
0.3	Subsystem slip requires workaround.	> 2 months	Within budgeted range.	>3%	Adequate alternatives exist.	Minor reduction.
0.2	Minor subsystem slip.	> 1 month	Minor.	>2%	Many adequate alternatives.	Minor to none.
0.1	Possible minor slip, noncritical path.	> 1/2 months	Negligible.	>1%	Many adequate alternatives.	No significant impact.
0.0	No schedule impact.	None	None.	None	Many adequate alternatives.	None.

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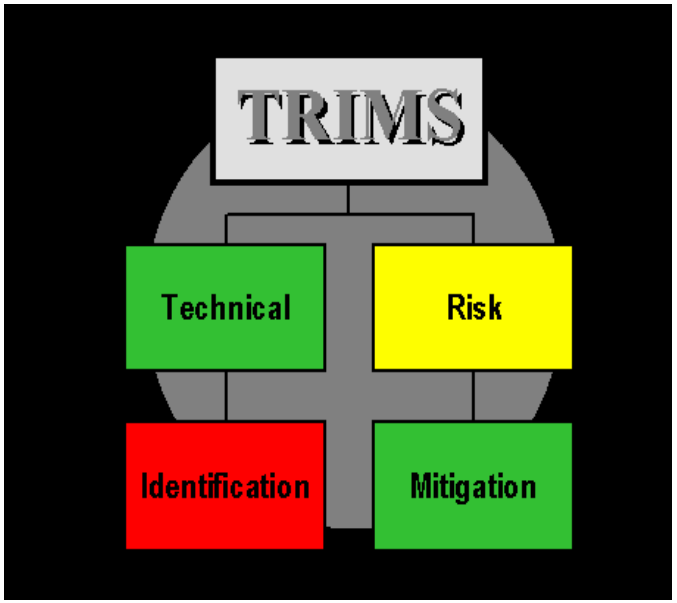
Risk Management Methodology - Beta testing

RATING	SOFTWARE	TECHNOLOGY	HARDWARE	REQUIREMENTS	TESTING	FREQUENCY
0.9	Extensive new complex S/W for new untested applications.	Maximum technology/ maximum capability.	Theoretical design based on advanced research.	Good probability of significant deficiencies in meeting requirements.	Technology not tested.	Frequent * Likely to occur Frequently ** Continuously Experienced.
0.8	Extensive S/W development, new approach, new language.	Theoretical technology.	New theoretical design.	Good probability of some moderate deficiencies in meeting all requirements.	Approach not tested.	
0.7	Extensive S/W development, - beyond experience base.	Newer technology.	All new design.	Moderate chance of moderate deficiencies in meeting all requirements.	Unimproved design has been tested.	Probable * Will occur several times in lifetime ** Will occur frequently
0.6	Major changes in S/W development approach and application.	Available technology, feasible by analogy.	New design to moderately improve existing design.	Moderate chance of minor requirement deficiencies.	Other analogous items have been tested.	
0.5	Readily adaptable S/W approach, conversion from similar application, expanded to new application.	Existing technology and feasibility studies.	Major design change.	Some chance of minor requirement deficiencies.	Old design has been tested.	Occasional * Likely to occur Sometime in the life of an item ** Will occur several times
0.4	Extensive modification and tailoring of existing approach.	Proven technology and approach. Feasibility analysis complete.	Redesign, significant modifications.	Slight chance of minor requirement deficiencies.	Similar designs and technology have been tested.	
0.3	Slightly modified approach, language conversion.	Proven technology and approach, used some by design agent.	Existing proven components, recombined or minor mods in function.	Should meet all requirements with little margin.	Limited testing done on existing components.	Remote * Unlikely, but possible to occur in life of an item ** Unlikely, but can be reasonably expected to occur
0.2	Some modification of existing S/W approach.	Proven technology and approach with significant design agent experience.	Existing proven components, repackaged and/or minor usage variation.	Should meet all requirements, and exceed many.	Testing has been done on existing components.	
0.1	Minor revision and checkout of existing S/W.	Proven technology and approach with significant design agent experience.	Functional hardware. Mods in form only.	Will meet all requirements, exceeding many.	Thoroughly tested hardware.	Improbable * So unlikely, assume it may not occur ** Unlikely to occur but possible
0.0	Use of existing, checked out S/W.	Off the shelf hardware proven to operational environments.	Functional hardware.	Will exceed all requirements with margin.	Thoroughly tested and exceed reqmts.	

Mil-Std-882B: * Specific Individual Item ** Fleet or Inventory

Testing

Technical Risk Identification and Mitigation (TRIMS)



http://www.bmpcoe.org/pmws/download/trims.html

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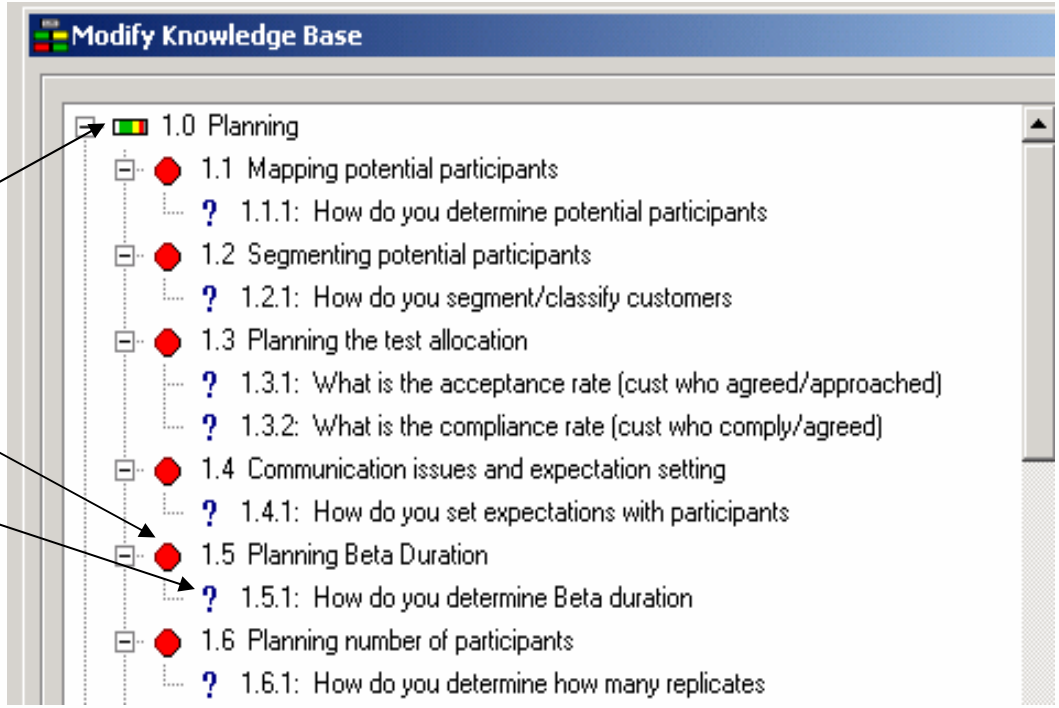
Technical Risk Identification and Mitigation (TRIMS)

- System file
  - Element File
    - Category
      - Template
      - >Question



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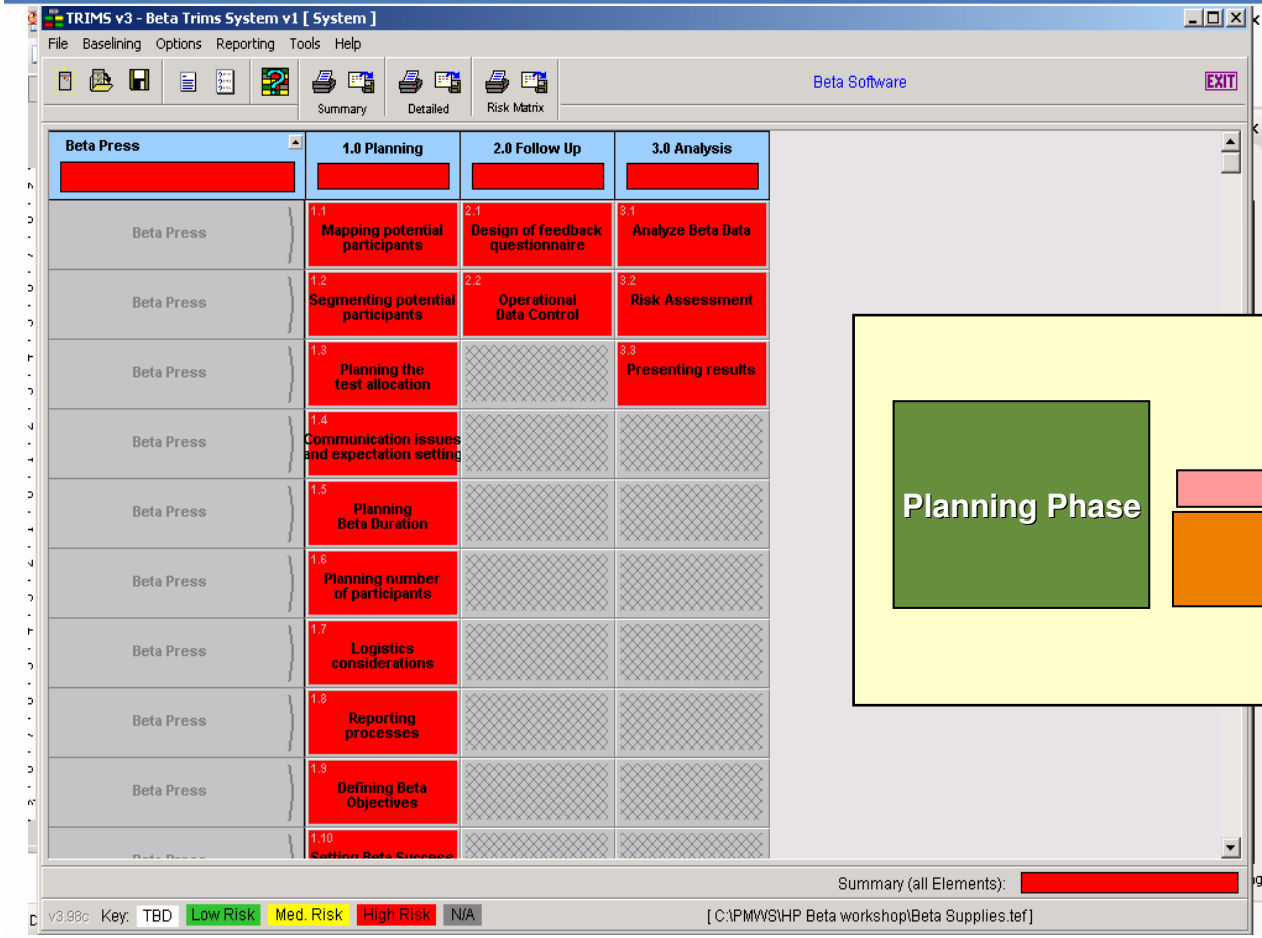
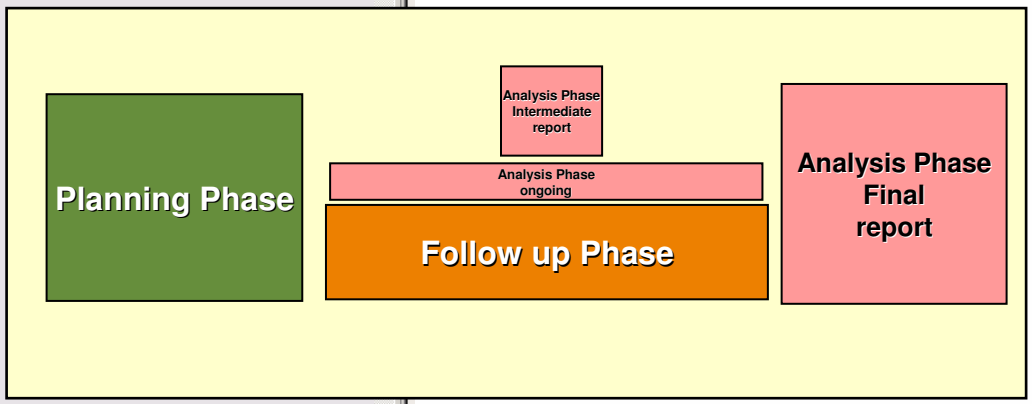
Risk Management Methodology - Beta testing





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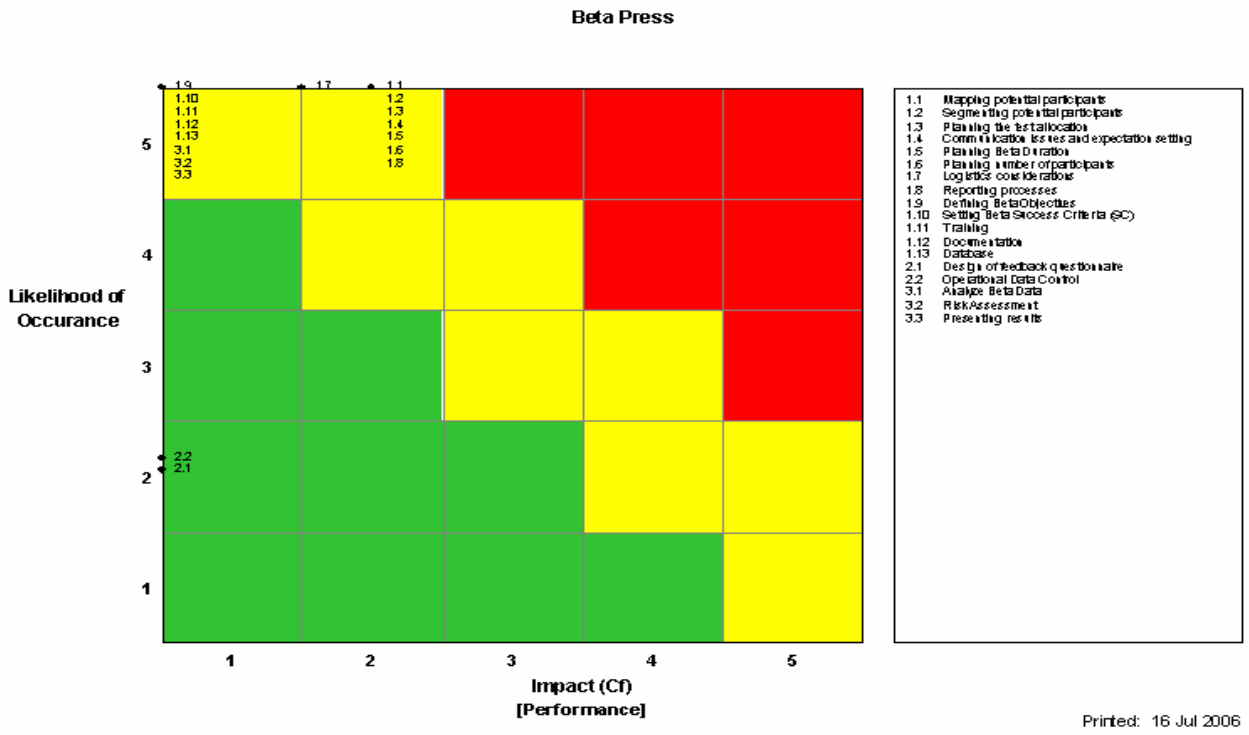
Risk Management Methodology - Beta testing



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What is needed to get actual results

- A Vision of what can be achieved
- An evidence based approach
- A methodology
- Tools supporting the methodology **(www.musing.eu**)
- An organizational structure to support the methodology
- The right people, at the right place, at the right time

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http://eu.wiley.com/WileyCDA/WileyTitle/productCd-0470018615.html

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In today's climate of intense industrial competition, certification and qualification are increasingly important. Statistical techniques in quality engineering play a vital role in these processes.

The Encyclopedia of Statistics in Quality and Reliability will offer an unparalleled reference source in this field of critical importance. It will be written and edited by leading authorities in the field and will address both fundamental and real-world issues and topics.

This landmark publication is currently planned as a three volume set with approximately 500 articles and will cover the following topics:

- Management of Quality and Business Statistics
- Process Capability and Measurement Systems Analysis
- Design of Experiments and Robust Design
- Sampling
- Process Control
- Reliability: Life Distribution Modelling and Accelerated Testing
- Reliability: Life Cycle and Warranty Cost Prediction
- System Reliability
- Health, Safety and Environmental Applications
- Statistical and Stochastic Modeling
- Computationally Intensive Methods and Simulation
- Basic Statistics for Quality and Reliability

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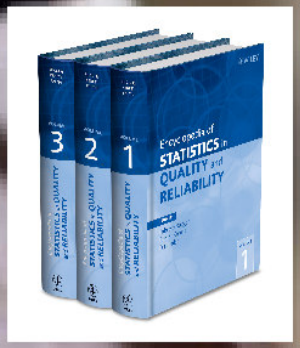

This Encyclopedia will be the latest in Wiley's successful program of reference works in applied statistics, which includes:

- Encyclopedia of Statistics in Behavioral Science
- Encyclopedia of Biostatistics
- Encyclopedia of Environmetrics
- Encyclopedia of Actuarial Science

Will be available in print and online

eqr339

Application of Statistical Process Control in Clinical Medicine and the Perils of Risk Adjustment

Introduction

The quality of a clinical process may be assessed provided it is in a state of statistical control, i.e., predictable. Control chart techniques originally developed for industrial process control [1] may be applied to develop and monitor the quality of a clinical process. However, if the quality measure/indicator used is an outcome measure, e.g., mortality following a coronary artery bypass graft operation, its value depends not only on the quality of the clinical process, but also on risk factors, e.g., severity of patient's disease, comorbidity, age, sex, etc. Va... risk-adjusted control charts may then be used although the results obtained should be consi... provisional, requiring further investigation.

Outcome results of several healthcare prov... (physicians, hospital departments, etc.) may be pared if the patients are assigned at random t... providers. Usually (but not always [3]) this is no... sible for practical and/or economical reasons. ... one has to use observational data. The influen... patient case-mix differences between the prov... therefore, has to be adjusted for prior to the ... parison [4]. This is usually (but not always [... achieved by regressing the provider category ... important risk factors on the outcome. The app... is fraught with problems. In the following w... present the statistical techniques used in this ... demonstrate the construction and subsequent u... a control chart by way of a straightforward exa... and illustrate and discuss the perils of risk adjust...

Methods

Control Chart

A control chart is used to characterize a cl... process and subsequently to monitor it. The ... depicts the values of a measurable quantity char... izing the process, e.g., the fraction of patients ...

eqr494

Monitoring of Safety Performance in the EU Railways: An Harmonized Framework to Set Safety Targets on the Basis of Lessons Learned from Accidents and Precursors

ERA, the Ambitious Projects on Safety of a Newcomer, under Directive 2004/49/EC

Railway is the safest land transport mode and one of the overall safest transport modes. Directive 2004/49/EC, on railway safety, has been put in place to support the creation of an integrated European railway area by facilitating market opening through the harmonization of safety management and regulation. Directive 2004/49/EC will also contribute to improve safety by: a cultural shift from a deterministic to a risk-based approach, the establishment of safety management systems, the introduction of a system for independent accident investigation, as well as by moving from self-regulation to regulation by independent authorities (National Safety Authorities – NSAs). This aims to create a basis for mutual trust ... is in charge of these projects, carried out in conjunction with industry and MSs in working groups of experts.

Development of Common Safety Indicators (CSIs) and Accidents Investigation

The working group on common safety indicators (CSIs) is developing and defining indicators structured as follows:

Safety performances

- type of accidents
- fatalities and injuries classified in categories of people
- precursors to accidents.

Economic aspects of safety performances

- societal benefits and costs of improving and worsening safety performances.

CSIs are expressed in total of events and consequences (fatalities and injuries) per unit of time (1 year), normalized mainly by traffic performances (train*km, passenger*km).

The flow of information and data exchange on safety issues between the concerned parties is completed by the activity of accidents investigation, carried out by National Investigation Bodies (NIBs) and communicated to ERA; the aim of this is to better understand the causes of accidents, which, together ...

eqr333

Quality in Critical Care Medicine

•Introduction

Critical care medicine is a growing element of modern hospital medicine. Critically ill patients consume about of 20% of hospital budgets and approximately 0.8% of the GNP in the United States and 0.2% in Canada [1]. It is therefore a very expensive part of hospital medicine.

Intensive care units (ICUs) can be structured in different ways: according to patient population (such as surgical vs medical, neuro, and burns) and according to organization of patient care (open vs closed units).

The recent interest in quality improvement in healthcare has not skipped the ICU environment and there are many opportunities to improve on the delivery of critical care provided in ICUs. To describe these, a brief look at the current issues that are problematic in caring for critically ill patients is needed.

The patients in the ICU are frequently the most complex patients in the hospital. These are the patients who require intensive monitoring and often complex and multiple therapeutic interventions. Many drug prescriptions are provided to these patients on a daily basis and this has been shown to be a ground for drug errors, which can lead to adverse patient outcomes [2].

Many factors impact the processes and therefore the outcomes of patients in the ICU. The physical design and equipment available, the organizational workflow of various medical services, and the interactions between the different members of the ICU team: physicians, nurses, pharmacists, physiotherapists, respiratory therapists, and social workers are all critical to achieve optimal outcome, and their availability as well as the communication between them all have a critical impact on the function of the ICU.

Determinants of Quality

process and clinical outcome. Process, includes the approach to patients with regard to using protocols, workflow of organization, and guidelines, and outcome primarily deals with the clinical outcome of patients admitted to the ICU, but also pertains to other markers of significance such as cost, length of stay, and resource use. An important component of outcome is patient and family satisfaction with the process in the ICU. An admission to intensive care is frequently a very dramatic episode in a person's life and the impact it has on the patient and family can and should be addressed, measured, and improved upon.

Physical design of the ICU can have significant effect on the workflow, on personal and patient satisfaction, and therefore on clinical outcome. Poorly designed work stations can lead to increased rate of medical errors, may impair communication, and increase the risk for nosocomial infections.

ICU Structure: Open *versus* Closed

Many ICUs are organized in an "open" manner. This means that the patients are admitted to the ICU by a primary physician who continues to carry the responsibility for all aspects of the patients' stay in the ICU. This implies that although consultants are used, the treatment of different patients may be quite diverse with some difficulty in implementing routines and protocols for the different clinical issues that may arise. "Closed" units have a primary ICU team that directs care of the patients when they are admitted to the ICU. These clinicians are "dedicated intensivists" and spend a major part of their time in caring for critically ill patients. Studies have shown differences in outcomes between closed and open units with an advantage to a closed unit [3].

The clinical process aspans the encounter with the patient from the decision on admission to the ICU and the therapy afforded to patients even before they are admitted to the ICU. Rivers and colleagues have shown that early goal directed therapy in patients with severe infections can dramatically reduce mortality. They applied this approach to critically ill patients ...


Thank you for
listening
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