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Reliability in Healthcare

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Defining “Reliability”

1. The measurable capability of an object to perform its intended function in the required time under specified conditions.

   (Handbook of Reliability Engineering, Igor Ushakov, editor)

2. The probability of a product’s performing without failure a specified function under given conditions for a specified period of time.

   (Quality Control Handbook, Joseph Juran, editor)

3. **The extent of failure-free operation over time.**

   (David Garvin)

Terminology Applied to IHI Work
(Different from the mathematical)

Unstable process:

– Failure in greater than 20% of opportunities

10^{-1}: 80% or 90% success

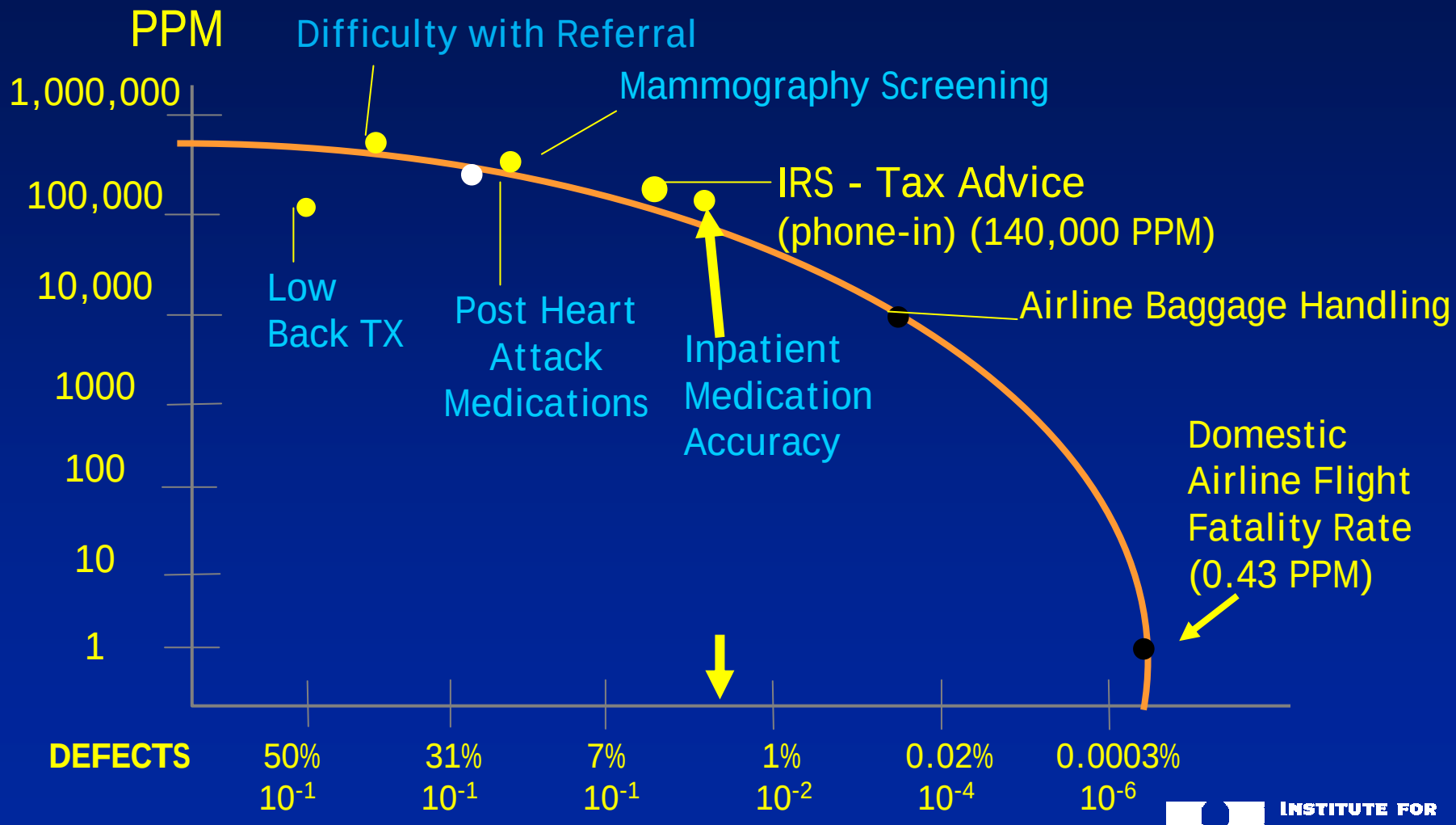
1 or 2 failures out of 10 opportunities

10^{-2}: 5 failures or less out of 100 opportunities

10^{-3}: 5 failures or less out of 1000 opportunities

10^{-4}: 5 failures or less out of 10,000 opportunities

Comparative Reliability Between Industries



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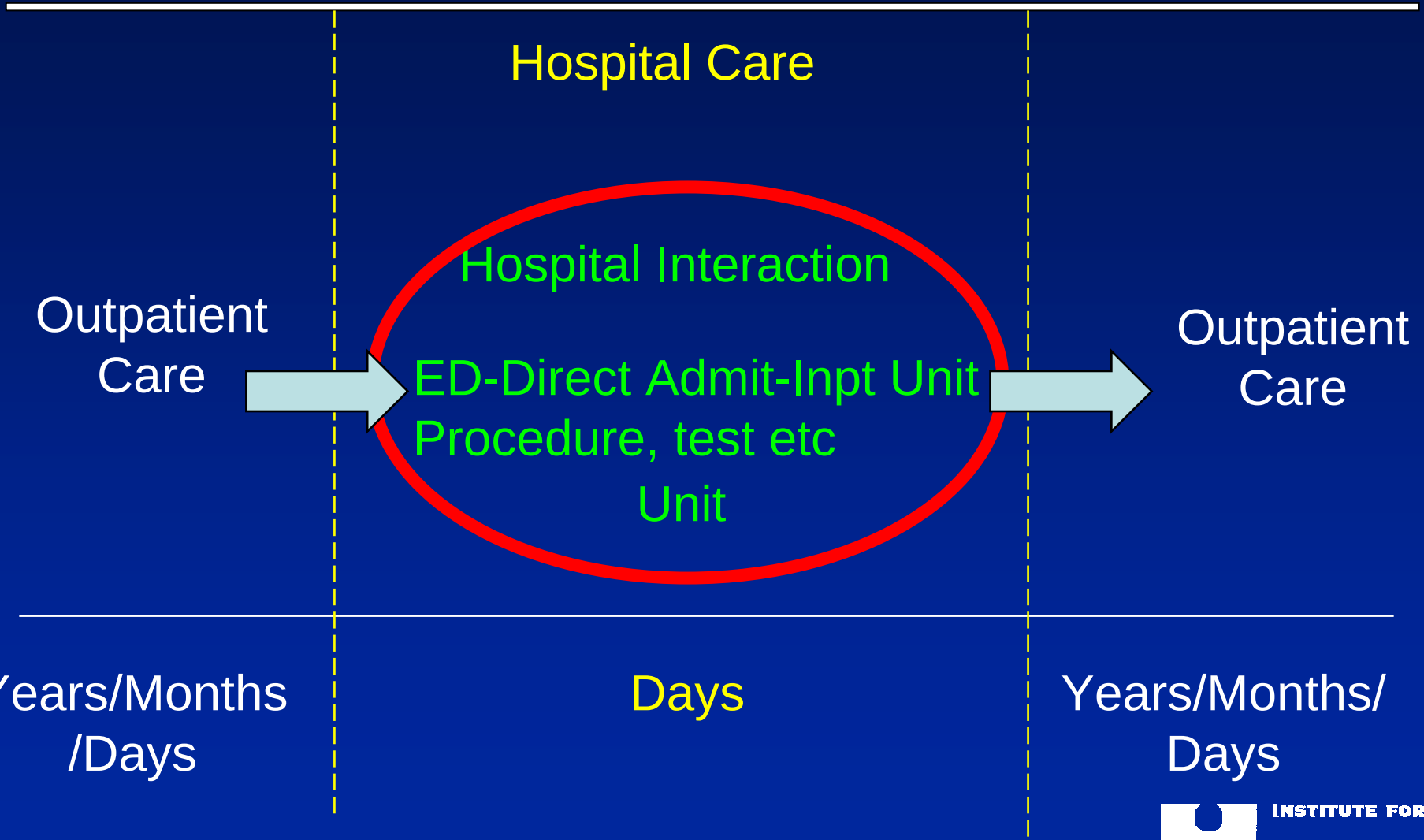
Health Care Process Reliabilities

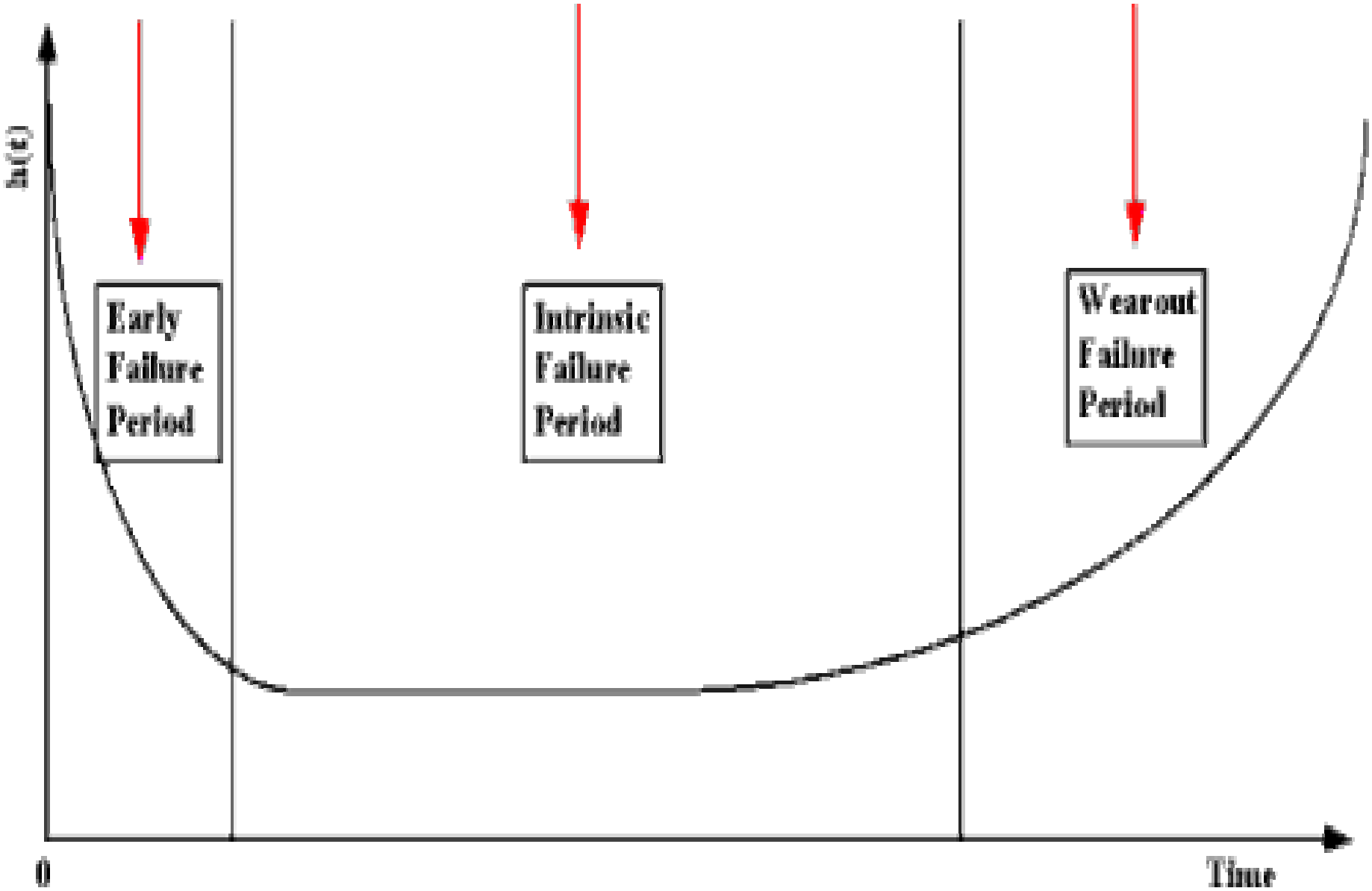
Reliability	Outcome/Process
10^{-1}	Beth McGlynn's study in *NEJM* Beta blockers for acute myocardial infarction >3 Hemoglobin A1c tests per two years
10^{-2}	Polypharmacy in the elderly Medication injuries Deaths in risky surgery
10^{-3}	Neonatal mortality General surgery deaths
10^{-4}	Deaths in routine anesthesia
10^{-5}	Deaths from major radiotherapy machine failures

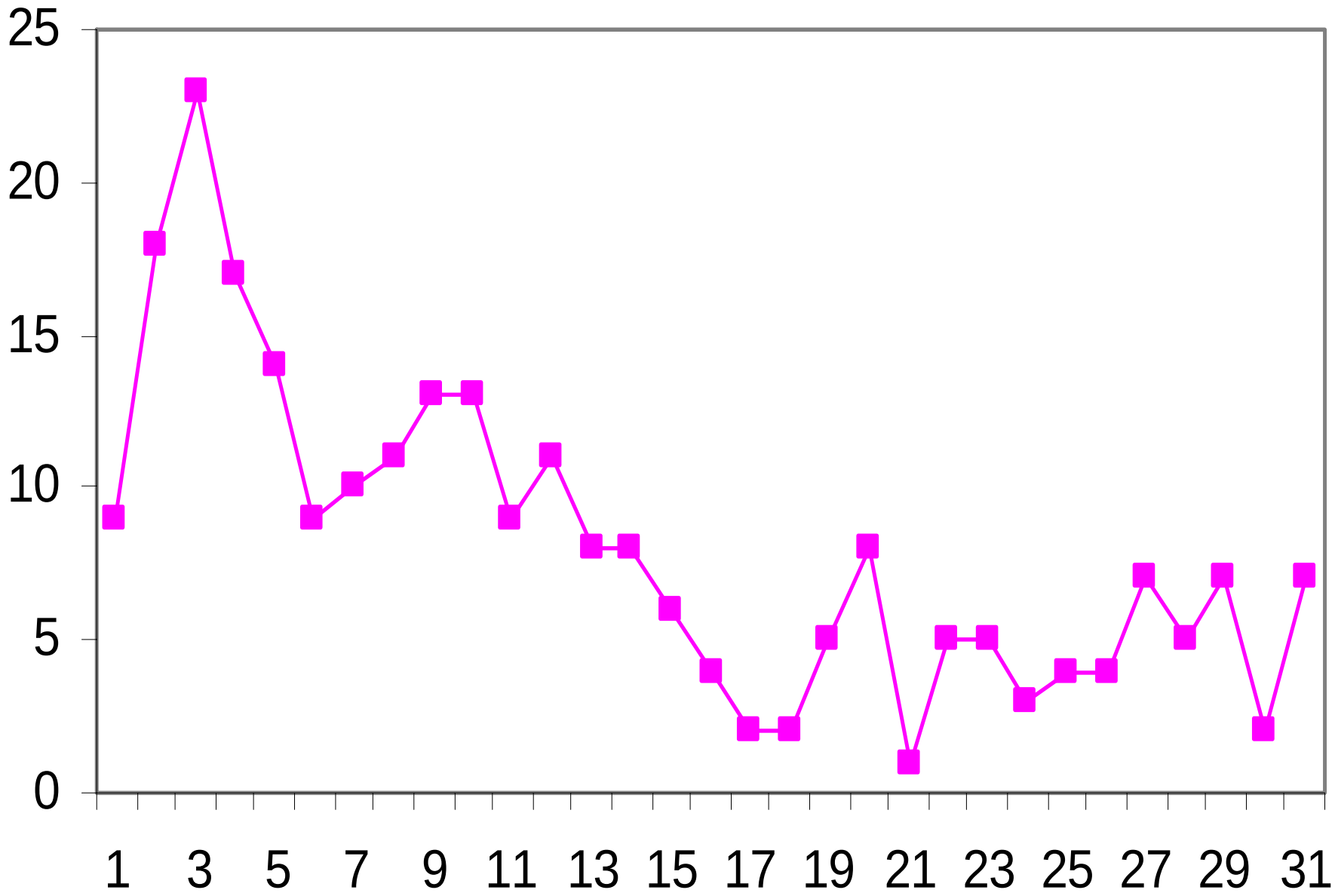
What is a defect or failure?

Defect free care over time from the patient's viewpoint



The Bathtub Curve




25
20
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29
31

Examples of Measures

- Process
  - ACE inhibitor for LVSD
  - Detailed discharge instructions
- Time
  - Prophylactic antibiotic 0-60 minutes before surgical incision
  - Door to balloon time ≤ 90 minutes
- Outcomes
  - MI mortality rate
  - Ventilator associated pneumonia

Measurement Strategies

Initial improvement and analysis

Ultimate goal

Approach	Explanation	Example
Separately	% patients meeting that measure	- Fraction patients receiving prophylactic antibiotic received one hour prior to surgical incision
Composite	$\frac{\text{Total measures met}}{\text{Total \# opportunities (across all patients)}}$	$\frac{\text{Total met}}{\text{3 measures x Number patients}}$
"All-or nothing"	Fraction patients meeting <u>all</u> measures (total met, 'perfect encounter')	<u>Fraction patients with ALL 3:</u> - Prophylactic antibiotic 1 hour prior - Prophylactic antibiotic selection for surgical patients - Antibiotics discontinued within 24 hours of surgery end time

Composite Measure

- Takes into account every individual measure for every patient
- Improvement will be seen as soon as even 1 individual measure improves

- DEFINITION

$$\frac{\text{Total opportunities met}}{\text{Total opportunities (\# measures x \# patients)}}$$

‘All or Nothing’ Measure

- Percentage of cases that achieve adherence to ALL individual quality measures.
- The ultimate measure – what percent of the times are we meeting all measures in a set for an individual patient?
- Upper limit is the lowest individual measure reliability. Lower limit is 0.
- Definition

$$\frac{\text{\# Patients with ALL measures met}}{\text{\# Patients}}$$

Factors & Causes of "un"-reliability

The focus on outcomes tends to exaggerate the reliability within healthcare giving clinicians a false sense of security.

‘All or Nothing’ Example

- CHF at St. Misery’s Medical Center:
  - 90% compliance smoking cessation
  - 70% compliance ACEI or ARB
  - 80% compliance LVEF assessment
  - 60% compliance with discharge instructions
- An upper bound for the aggregate reliability is the smallest level of compliance with any individual component, here 60% (discharge instructions).

Current improvement methods in healthcare are highly dependent on vigilance and hard work

Intent, Vigilance and Hard Work: 10^{-1} Performance

Designing basic failure prevention

- Common equipment, standard orders sheets
- Personal check lists
- Working harder next time
- Feedback of information on compliance
- Awareness and training

Permissive clinical autonomy creates wide performance margins

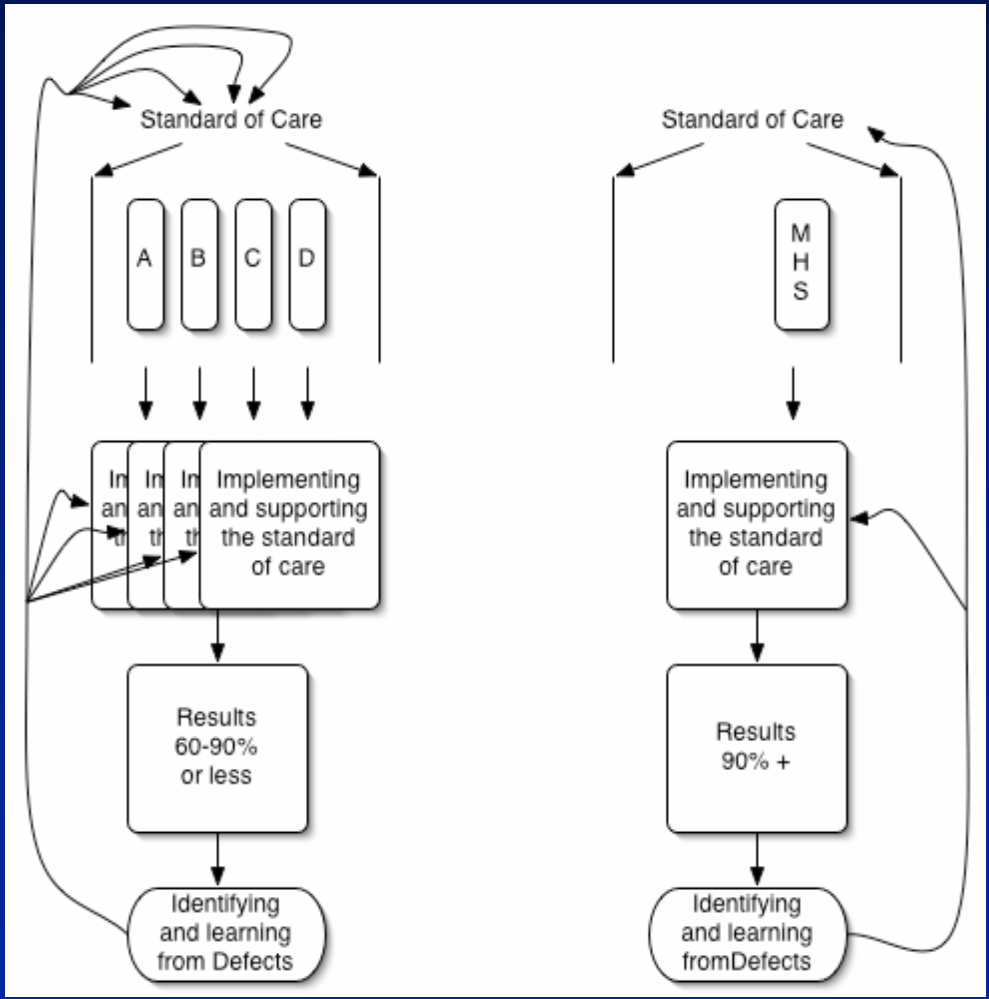
René Amalberti: Premises

- "Unconstrained" human performance (guided by personal discretion, only) is worse than 10^{-2}

- "Constrained" human performance (with certain limits on discretion) can reach reliability of 10^{-2} to 10^{-3}

Healthcare processes

Current - Variable, lots of autonomy not owned, poor if any feedback for improvement, constantly altered by individual changes, performance stable at low levels



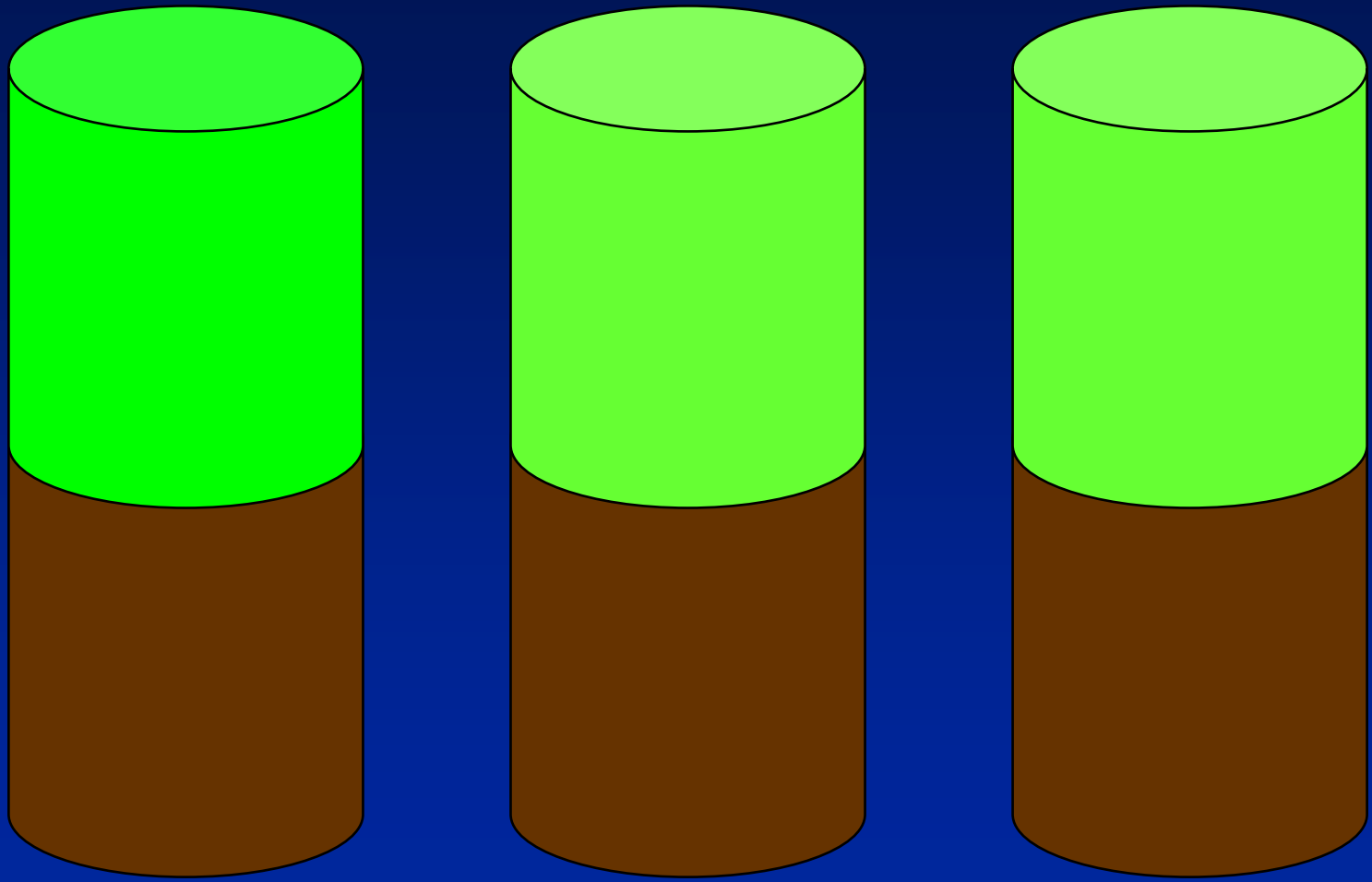
Desired – variation based on clinical criteria, no individual autonomy to change the process, process owned from start to finish, can learn from defects before harm occurs, constantly improved by collective wisdom - variation

Design of processes rarely accounts or plans for human factors

What are Human Factors?

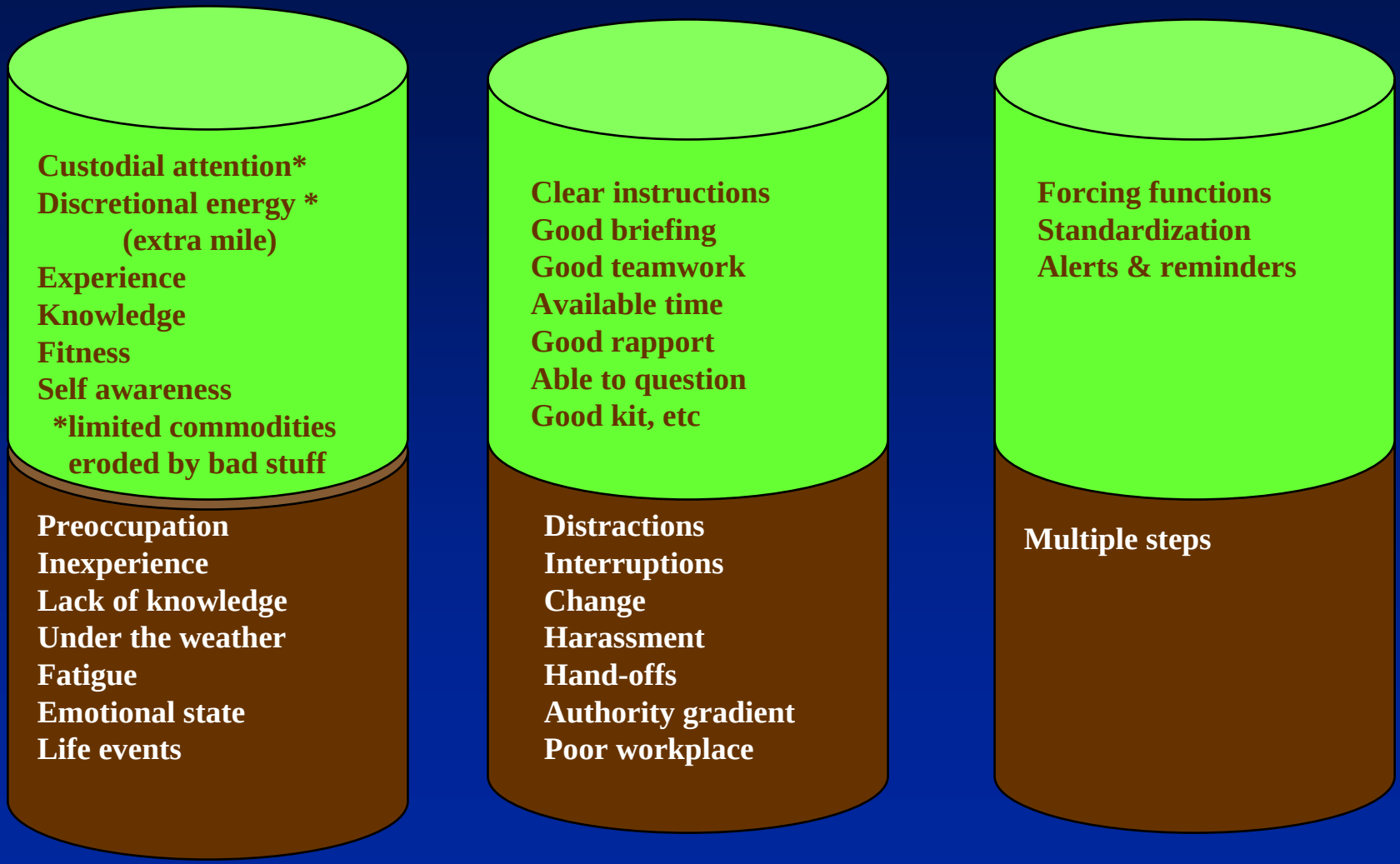
- Reliance on memory
- Distractions / interruptions
- Fatigue
- Sleep deprivation
- Shift work
- Lack of training and experience
- Overload
- Psychosocial factors

The Three Buckets – *James Reason*



SELF CONTEXT TASK

The Three Buckets —*James Reason*



Preventing Errors... The Role of Complexity

Probability of Performing Perfectly

Probability of Success, Each Element

No. Elements	0.95	0.990	0.999	0.9999
1	0.95	0.990	0.999	0.9999
25	0.28	0.78	0.98	0.998
50	0.08	0.61	0.95	0.995
100	0.006	0.37	0.90	0.99

Human Factors and Reliability Science: 10^{-2} Performance

- Decision aids and reminders built into the system
- Desired action the default(based on evidence)
- Redundancy
- Scheduling
- Taking advantage of habits and patterns
- Standardization of process

Design of Safe and Reliable Systems of Care: Prevent-Identify-Mitigate*

Prevent → Design the system to prevent failure

Identify → Design procedures and relationships to make failures visible when they do occur so that they may be intercepted before causing harm

Mitigate → Design procedures and build capabilities for mitigating the harm caused by failures when they are not detected and intercepted

*Earl Weiner U of Miami
Espinosa/Nolan BMJ March 2000

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Applying the Concepts

Start Work in a Segment

- Identify a segment of patients in the population
  - Homogenous for design needs (process will be the same in most cases)
  - Identification is easiest
  - Constitute large percent of population
- Design for the segment first to learn reliable design…then spread to the population

New Standardization Concepts

- Standardization to provide appropriate infrastructure
  - "What" based on good medical evidence
  - "How" does not need medical evidence but systems knowledge
- Initial standardized protocols: small time investment by experts
  - Customization initially: required and encouraged
  - Changes are possible when generally accepted - but monitored
- Defects are used to move to a learning system

New Standardization Concepts

- Critical failure modes drive customization
- Organizational maturity drives the complexity of the standardization
- Leadership must drive expectation of standardization
- Model shifts
  - From hope for clinicians to “opt in”
  - To requirement of an explanation if “opt out”
    - “Opt Out” reasons used to remodel process
- Designated process owner

Examples of Strategies

TOPIC	RELIABILITY CONCEPT	STRATEGY
Central Line Bundle	Standardization, decreased reliance on memory, forcing function	One kit or cart with all supplies needed (and no supplies not in compliance)
AMI “one call”	Standardization, less steps/complexity, decreased reliance on memory	One call notifies physicians and cath lab team
SSI d/c abx	Opt out rather than opt in, standardization	Abx auto discontinued
SSI pre-op dose abx	Taking advantage of habits & patterns (human factors)	Dose of antibiotic started at door to OR
MRSA contact precautions	Visual reminder	“Red line” on floor indicating zone for contact precautions required
Others?		

IF THE SCIENCE IS RIGHT…
OUTCOMES WILL FOLLOW

Successful Outcome Improvement

Hackensack University Medical Center (HUMC)

Through their Cardiac Service Line, developed standardized processes for AMI care

- Composite score increased from 72% in the first quarter of 2003 to 91% by the fourth quarter of 2003
  - (as calculated by CMS: aggregate of the key measures).

- AMI inpatient mortality decreased from 7% to 5.2% in the same time period.

•Hackensack University Medical Center AMI Report, Sept 10, 2004

Successful Outcome Improvement

McLeod Regional Medical Center

- Developed protocols based on the evidence,
  - Percent of patients who received “perfect care” (all AMI key measures) increased from 80% in January 2001 to 100% by November 2003.
  - Average inpatient mortality rate for AMI has been 4% for the past year, below the CMS reported average of 7% in 2003.

What Should You Do?

- Require Human Factors and Reliability Science design concepts for all projects
- Focus on process rather than outcomes
  - If the science is right the outcomes will follow
- Delineate clear performance margins
  - Argue about the “how” rather than the “what”
- Identify a core set of Model 10-2 processes that you will get right
  - measures such as HF, AMI, critical care bundles
  - expectations of 10^{-2} for the “all-or-nothing” measurement

Level of Reliability: How high do we need to go?

- Ventilator & Central Line bundles
  - a group of interventions that, when implemented together, result in better outcomes than when implemented individually.

- 10^{-2} performance with the PROCESS
  - Adverse outcome to ZERO

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Why not 10^{-2} or better for your patients?