



WHY PATIENT SAFETY AND QUALITY IMPROVEMENT A MUST IN HEALTHCARE?

AURO VISWABANDYA, MD, DM, FRCP, FRCPC.

MEDICAL DIRECTOR - QUALITY FOR BMT AND IEC THERAPY,

STAFF PHYSICIAN; DIVISION OF MEDICAL ONCOLOGY & HEMATOLOGY,

PRINCESS MARGARET CANCER CENTRE

DEPARTMENT OF MEDICINE,

UNIVERSITY OF TORONTO,

CANADA.

Declaration and Conflict of Interest

I have no conflict of interest.

I am not going to discuss about Regulatory and Accreditation aspect.

I am currently doing a Masters course in Health Quality and Safety (MHQS) at Harvard Medical School, Boston.

I am an Active Clinical FACT Inspector.







Objectives...

Part-I

- Why safety is important and how to establish a safe environment in healthcare?
- How to investigate an 'Unsafe' event?

Part -II

- What do we mean by Quality improvement, Quality Methodologies and Quality improvement Tools?
- What are fundamental steps in Quality Improvement?

Libby Zion 1984



- An 18-year-old Medical student arrived at a Teaching Hospital Emergency department with fever.
- She died within 5 hours.
- Her family raised concerns that she died because of unsafe care and a lack of supervision of the medical staff
- A grand jury investigation was opened.

January: Phenelzine for stress

February: ASA-Oxycodone – For Tooth
Erythromycin & Chlorpheniramine – For
Otitis

Also on Imipramine, Diazepam and Tetracycline

March: Febrile x 3 days

Arrives to ER at 11.30 pm Seen by the JR who was not aware about all the previous drugs.

O/E -Hyperemic tympanic membrane, murmur, petechiae on thigh, leukocytosis, treated for sepsis, Admitted to Medical Service: Noted to be agitated and shivering.

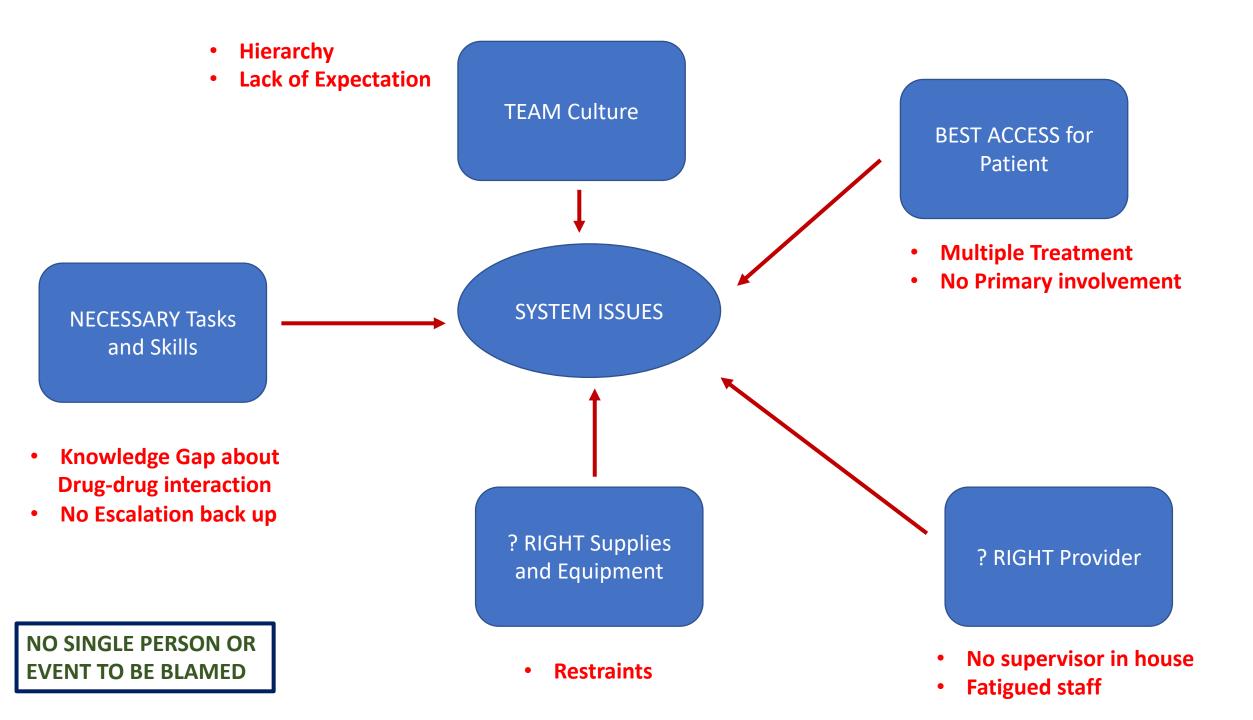
3.30 am – Given Meperidine - More confused4.30 am – More restless. Not seen by MD.Restraints and Haloperidol

4.30 -6.00 am – Quiet but still febrile

6.30 am -Suffers a cardiac arrest and dies.

Medical Examiner's Report:

- 1. Hyperpyrexia
- 2. Cardiovascular collapse



SPECIAL ARTICLES

INCIDENCE OF ADVERSE EVENTS AND NEGLIGENCE IN HOSPITALIZED PATIENTS

Results of the Harvard Medical Practice Study I

TROYEN A. BRENNAN, M.P.H., M.D., J.D., LUCIAN L. LEAPE, M.D., NAN M. LAIRD, Ph.D., LIESI HEBERT, Sc.D., A. RUSSELL LOCALIO, J.D., M.S., M.P.H., ANN G. LAWTHERS, Sc.D., JOSEPH P. NEWHOUSE, Ph.D., PAUL C. WEILER, LL.M., AND HOWARD H. HIATT, M.D.

Abstract *Background.* As part of an interdisciplinary study of medical injury and malpractice litigation, we estimated the incidence of adverse events, defined as injuries caused by medical management, and of the subgroup of such injuries that resulted from negligent or substandard care.

Methods. We reviewed 30,121 randomly selected rec-

permanently disabling injuries and 13.6 percent led to death. The percentage of adverse events attributable to negligence increased in the categories of more severe injuries (Wald test $\chi^2 = 21.04$, P<0.0001). Using weighted totals, we estimated that among the 2,671,863 patients discharged from New York hospitals in 1984 there were 98,609 adverse events and 27,179 adverse events

- 30,121 randomly selected patient's records.
- Total of 98,609 adverse events in the US

1994:

Drug Complications -19% Wound infection -14% Operation related - 48%

Medical cases more likely to be negligent.

Diagnostic mishaps, non surgical
therapeutics, events in the ED and errors in
management.

Vol. 324 No. 6

ADVERSE EVENTS IN HOSPITALIZED PATIENTS — LEAPE ET AL.

377

THE NATURE OF ADVERSE EVENTS IN HOSPITALIZED PATIENTS

Results of the Harvard Medical Practice Study II

LUCIAN L. LEAPE, M.D., TROYEN A. BRENNAN, M.D., J.D., M.P.H., NAN LAIRD, Ph.D., ANN G. LAWTHERS, Sc.D., A. RUSSELL LOCALIO, J.D., M.P.H., BENJAMIN A. BARNES, M.D., LIESI HEBERT, Sc.D., JOSEPH P. NEWHOUSE, Ph.D., PAUL C. WEILER, LL.M., AND HOWARD HIATT, M.D.

Abstract Background. In a sample of 30,195 randomly selected hospital records, we identified 1133 patients (3.7 percent) with disabling injuries caused by medical treatment. We report here an analysis of these adverse events and their relation to error, negligence, and disability.

Methods. Two physician-reviewers independently identified the adverse events and evaluated them with respect to negligence, errors in management, and extent of disability. One of the authors classified each event according to type of injury. We tested the significance of differences in rates of pedligence and disability among catego-

gery were less likely to be caused by negligence (17 percent) than nonsurgical ones (37 percent). The proportion of adverse events due to negligence was highest for diagnostic mishaps (75 percent), noninvasive therapeutic mishaps ("errors of omission") (77 percent), and events occurring in the emergency room (70 percent). Errors in management were identified for 58 percent of the adverse events, among which nearly half were attributed to negligence.

Conclusions. Although the prevention of many adverse events must await improvements in medical knowl-

Betsey Lehman -1994

Reporter received overdose of Chemotherapy

4000 mg/m2 over 4 days

- Doctors left; Family sued
- Dana Farber Cancer Institute

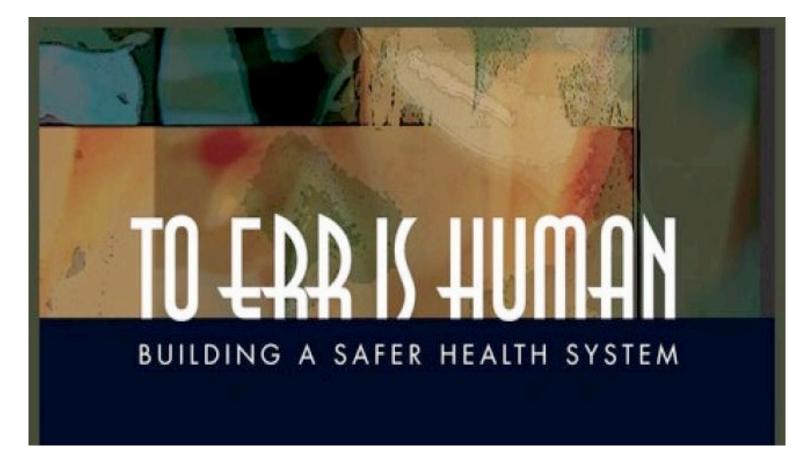
Safety over convenience
Oversight of safety
Supervision
Increased Transparency: Patient and Family council





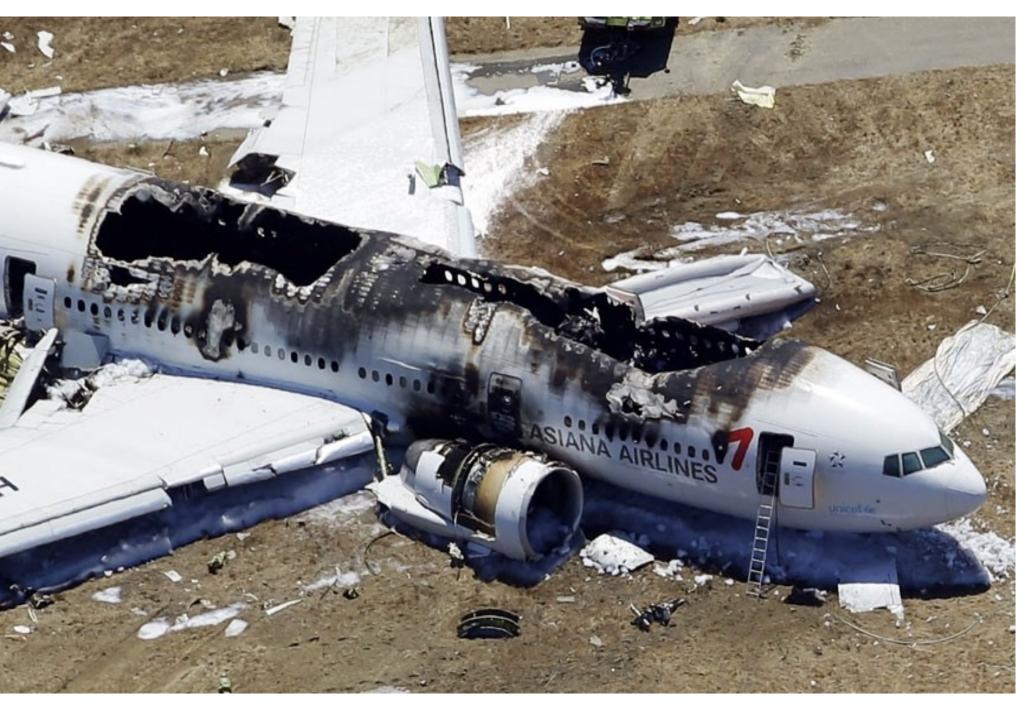
DANA-FARBER ADMITS DRUG OVERDOSE CAUSED DEATH OF GLOBE COLUMNIST, DAMAGE TO SECOND WOMAN

When 39-year-old Betsy A. Lehman died suddenly last Dec. 3 at Boston's Dana-Farber Cancer Institute, near the end of a grueling three-month treatment for breast cancer, it seemed a tragic reminder of the risks and limits of high-stakes cancer care. In fact, it was something very different. The death of Lehman, a Boston Globe health columnist, was due to a horrendous mistake: a massive overdose of a powerful anticancer drug that ravaged her heart, causing it to fail suddenly....

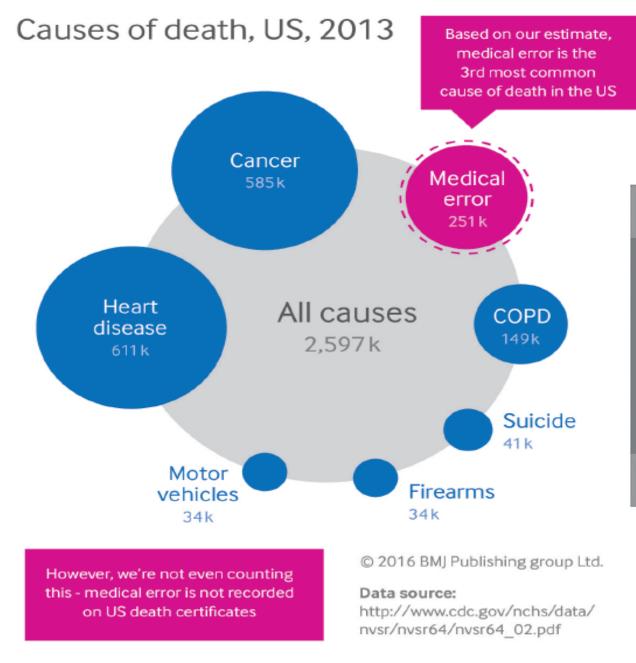


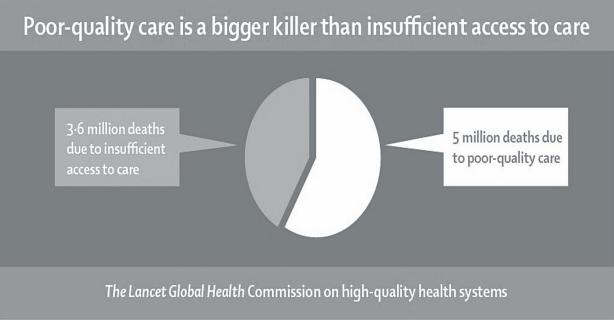
1999

- 44,000 98,000 Americans die each year as a result of medical error.
- Costs of \$ 17-29 billion for inpatient care
- Hidden Cost (Loss of Trust; loss of provider satisfaction; loss to the society)



A BOEING 747 CRASH EVERY ALTERNATE DAY / WEEK!!



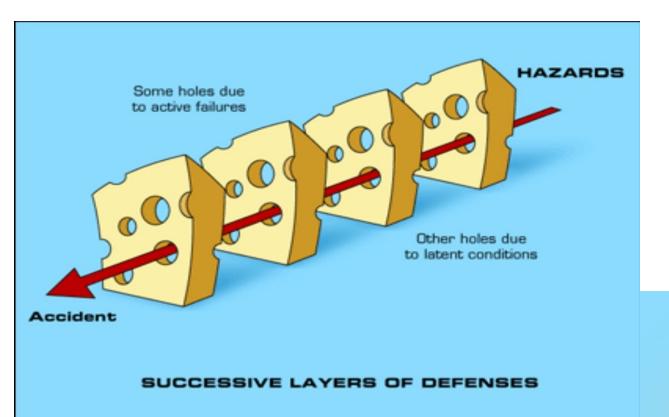


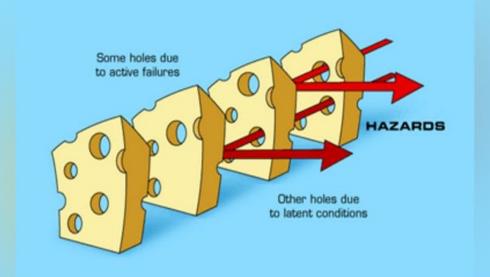
Kruk ME et al, The Lancet, Sept 2018

5 MILLIONS DIE GLOBALLY DUE TO POOR-QUALITY CARE.

Fig 1 Most common causes of death in the United States, 2013²

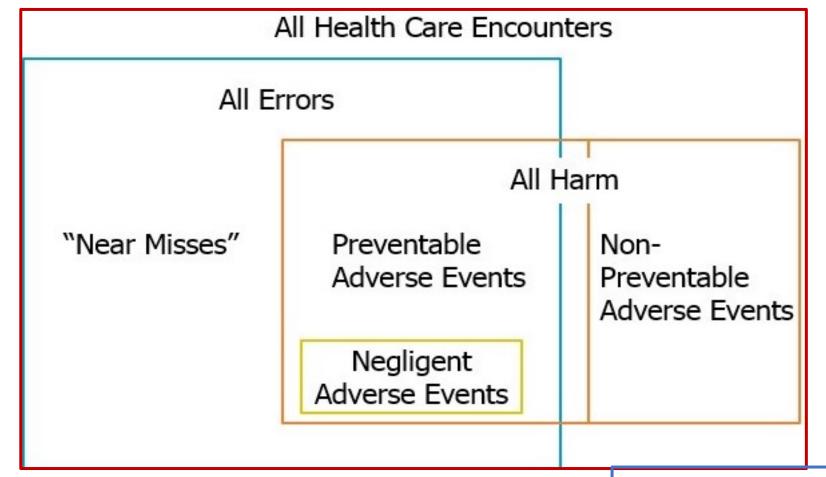
SWISS CHEESE MODEL – JAMES REASON





SUCCESSIVE LAYERS OF DEFENSES

ADVERSE EVENTS: Anytime a patient suffers a negative outcome from an interaction with the healthcare system



- HARM
- NO HARM
- NEAR MISSES

Preventable Adverse Events:

Medication Errors
Procedural Errors
Diagnostic Errors

Unsafe Acts Errors or violations committed in the presence of a potential hazard **Violations Errors** Deliberate deviation from an Failure to carry out a planned action as intended or application of an operating procedure, incorrect plan standard, or rules Action does not go as Action goes as intended, but is wrong intended Mistakes Slips Lapses Unobservable, or mental, error Error in decision making or Observable error of execution incorrect planning of execution Rule-based **Knowledge-based** Error stemming from a lack of Error in applying knowledge knowledge correctly

Taking a new perspective

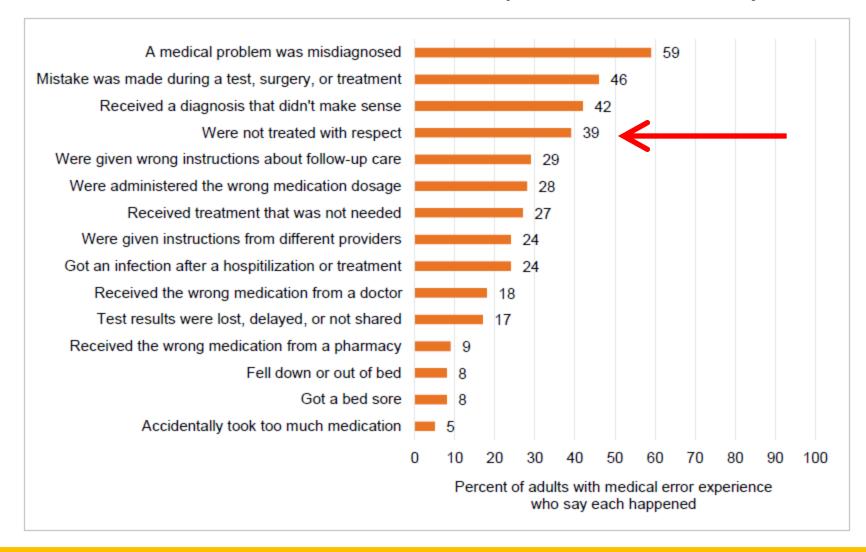
Patients & families experiencing harmful events ≥5 yrs ago report...

66% lasting physical impacts

59% altered life/view of self
53% vivid memories
50% loss of trust in healthcare
50% anger
34% grief
34% "psychological scars" (depression, suicidality, paranoia, PTSD)
31% financial impacts
31% altered healthcare seeking behaviors
28% self-blame

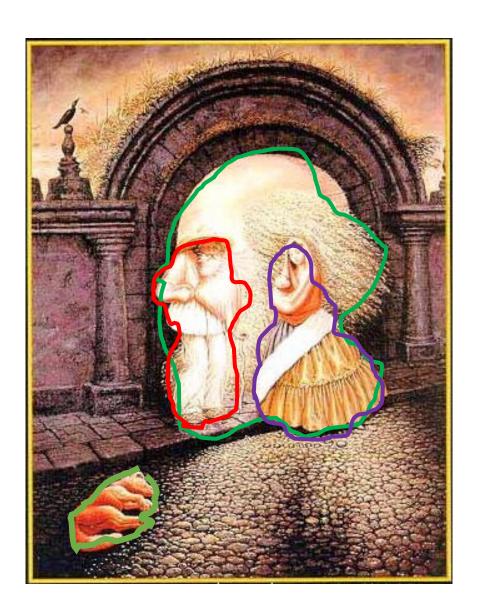
Taking a new perspective

Americans asked about the nature of their experience with error say...



WHAT DO YOU SEE?

TWO COMPETING SYSTEMS OF THOUGHT



System 1

- Automatic
- Intuitive
- Involuntary
- Effortless
- Ex. Driving "How did I get here?"
- Less energy

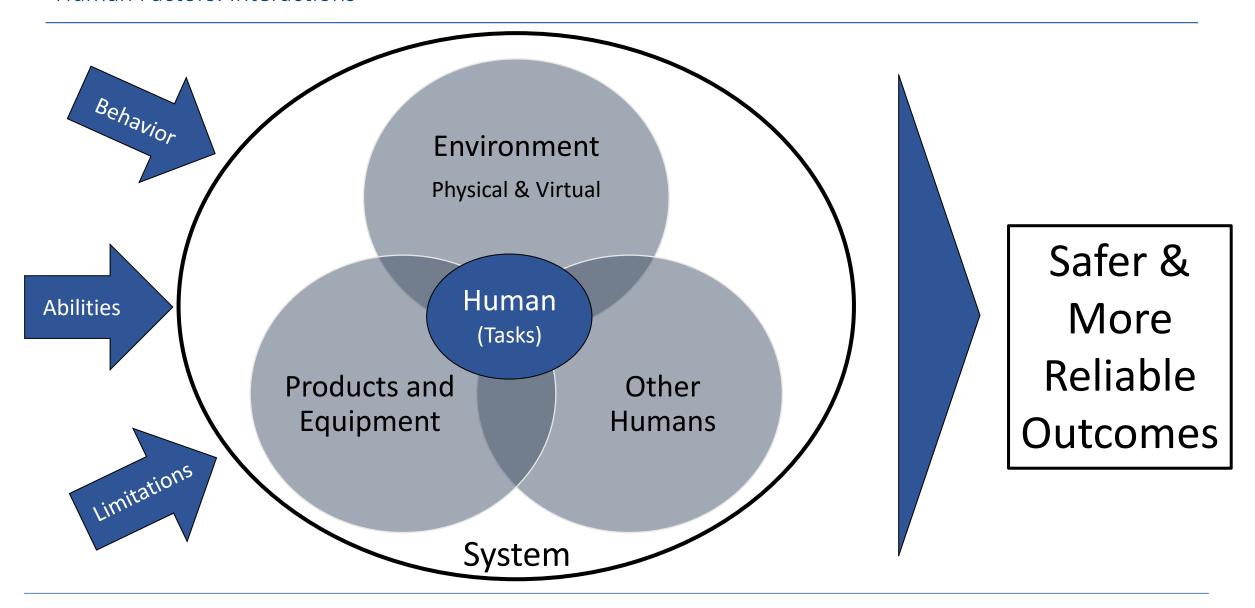


Constant Conflict

System 2

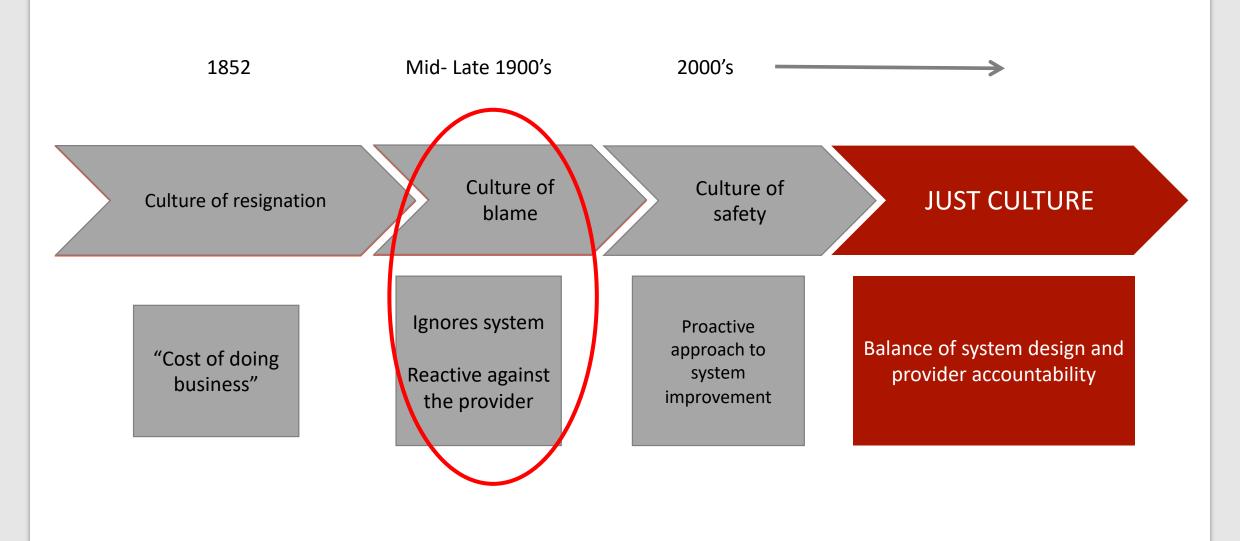
- Deliberating
- Problem solving
- Reasoning
- Concentrating
- Ex. Solving a complex math problem
- More energy

1.Kahneman, D. (2011). Thinking, fast and slow.

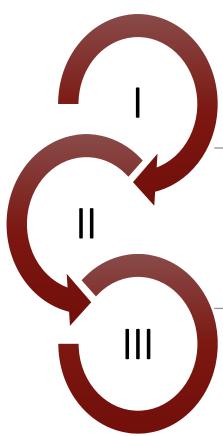


Stress, Fatigue, Distraction, Noise, Boredom, Interruption, Fixation, Reliance on Memory, issues related to communication

AN EVOLUTION OF CULTURE



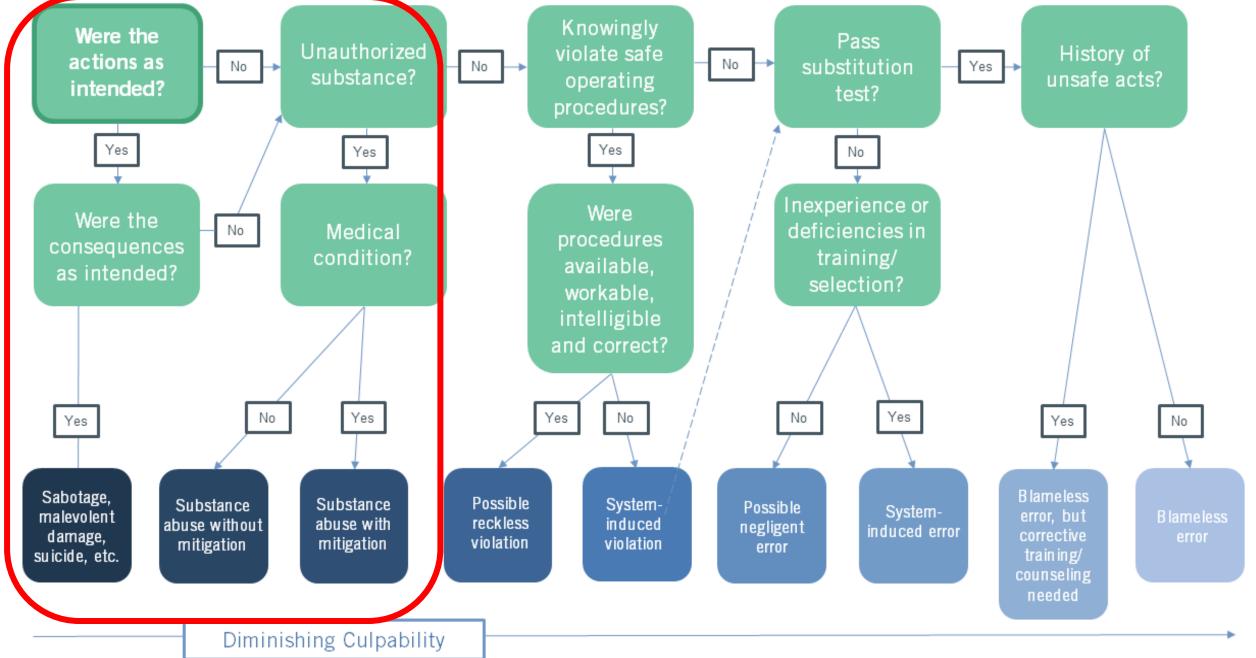
JUST CULTURE



A culture that supports and rewards people for sharing essential safety-related information

Providers trust that they will not be blamed for system issues

Systems are constructed to support providers, but providers are accountable for their behavior





Just Culture Responses

Human Error

Product of Our Current System Design and Behavioral Choices

Manage through changes in:

- Choices
- Processes
- Procedures
- Training
- Design
- Environment

At-Risk Behavior

A Choice: Risk Believed Insignificant or Justified

Manage through:

- Removing incentives for at-risk behaviors
- Creating incentives for healthy behaviors
- Increasing situational awareness

Coach

Reckless Behavior

Conscious Disregard of Substantial and Unjustifiable Risk

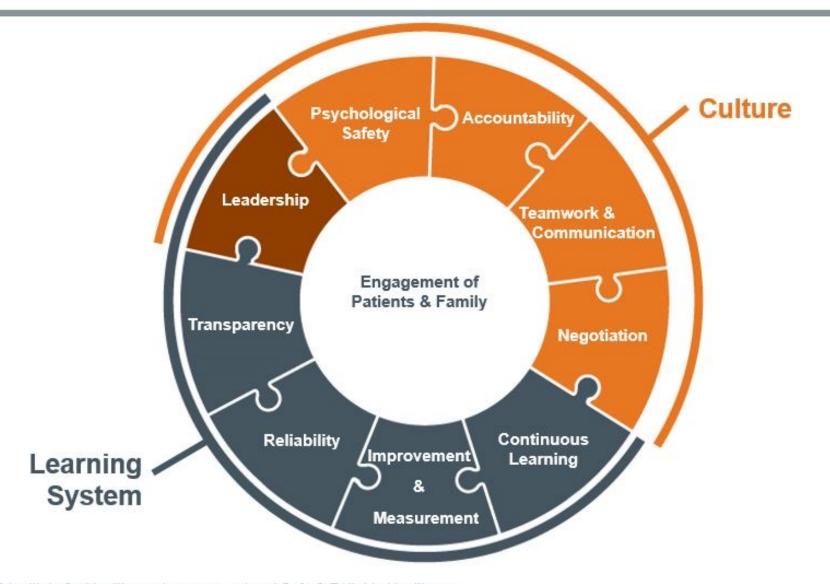
Manage through:

- Remedial action
- Punitive action

Punish

Console

Framework for Safe, Reliable, and Effective Care



CULTURE

+
SYSTEM

=
SAFETY

© Institute for Healthcare Improvement and Safe & Reliable Healthcare

Source: Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available on ihi.org)



EVENT ANALYSIS



1. Decision to Review



2. Select People and Gather Data



3. Determine Incident Chronology



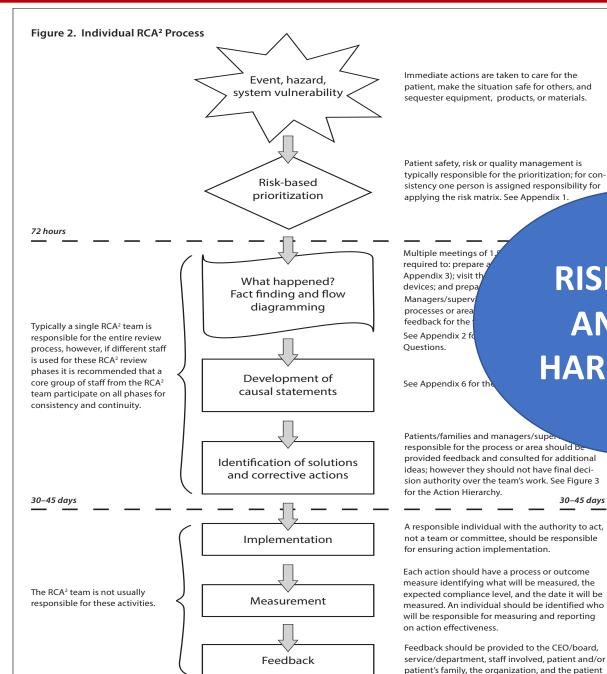
4. Identify Care Delivery Problems



5. Identify Contributory Factors



6. Making Recommendations & Developing an Action Plan



Catastrophic

RISK BASED

AND NOT

HARM BASED

30-45 days

safety organization (if relevant).

Patients with Actual or Potential:

Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime. Any of the adverse events defined by the Joint Commission as reviewable "Sentinel Events" should also be considered in this category.

> ath; or hospitalization of three or more visitors spitalization of three or more staff*

tial: Increased length of stay or or two patients nent for one or two visitors (less

me or restricted duty injuries or

hage more than \$10,000, but less than

Maior

Patients with Actual or Potential:

Permanent **lessening** of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions

(i.e., acts of commission or omission) or any of the following:

- a. Disfigurement
- b. Surgical intervention required
- c. Increased length of stay for three or more patients
- d. Increased level of care for three or more patients

Visitors: Hospitalization of one or two visitors

Staff: Hospitalization of one or two staff **or** three or more staff experiencing lost time or restricted duty injuries or

Equipment or facility: Damage equal to or more than \$100.000***

Minor

Patients with Actual or Potential: No injury, nor increased length of stay nor increased level of care

Visitors: Evaluated and no treatment required or refused

restricted duty injuries nor illnesses

any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat and/or air conditioning)**,

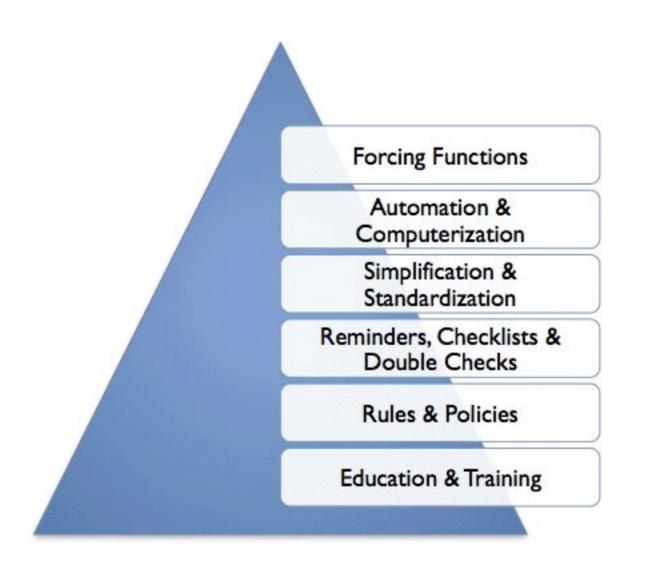
Staff: First aid treatment only with no lost time, nor

Equipment or facility: Damage less than \$10,000 or loss of

3. How the Safety Assessment Codes (SAC) Matrix Looks

Probability and Severity	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

HIERARCHY OF INTERVENTION EFFECTIVENESS

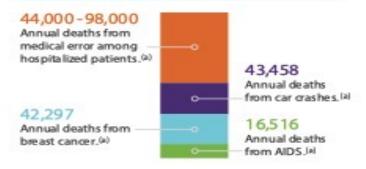


FREE FROM HARM:

ACCELERATING PATIENT SAFETY IMPROVEMENT FIFTEEN YEARS AFTER TO ERR IS HUMAN Report of an expert panel convened by the National Patient Safety Foundation argues for looking at morbidity as well as mortality caused by medical errors and going beyond hospitals to improve safety across the continuum of care.



TO ERR IS HUMAN FRAMED PATIENT SAFETY AS A SERIOUS PUBLIC HEALTH ISSUE (1999 ESTIMATES)



BY SOME MEASURES, HEALTH CARE HAS GOTTEN SAFER SINCE TO ERR IS HUMAN



1.3 Million

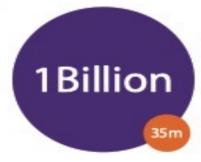
Estimated reduction in hospital-acquired conditions (2011-2013) as a result of the federal Partnership for Patients initiative. [b]

TO UNDERSTAND THE FULL IMPACT OF PATIENT SAFETY PROBLEMS, WE MUST LOOK AT BOTH MORTALITY AND MORBIDITY



1in10

patients develops a health care acquired condition (such as infection, pressure ulcer, fall, adverse drug event) during hospitalization.^[b] BUT WE MUST LOOK BEYOND HOSPITALS TO THE FULL CARE CONTINUUM



Roughly 1 billion ambulatory visits occur in the US each year.(c)



About 35 million hospital admissions occur annually.(c)

ADVANCEMENT IN PATIENT SAFETY REQUIRES AN OVERARCHING SHIFT FROM REACTIVE, PIECEMEAL INTERVENTIONS TO A TOTAL SYSTEMS APPROACH TO SAFETY^(d)

- Ensure that leaders establish and sustain a safety culture.
- Create centralized and coordinated oversight of patient safety.
- 3 Create a common set of safety metrics that reflect meaningful outcomes.
- Increase funding for research in patient safety and implementation science.
- 5 Address safety across the entire care continuum.
- 6 Support the health care workforce.
- Partner with patients and families for the safest care.
- 8 Ensure that technology is safe and optimized to improve patients afety.

Sources: (a) Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press, 2000. (b) 2013 Annual Hospital-Acquired Condition Rate and Estimates of Cost Savings and Deaths Averted From 2010 to 2013. Rockville, MD: Agency for Healthcare Research and Quality; October 2015. AHRQ Publication No. 16-0006-EF. http://www.ahrq.gov/professionals/quality-patient-safety/pfp/index.html. (c) National Center for Health Statistics. Faststats A-Z. Ambulatory Care and Hospital Utilization. Available at: http://www.cdc.gov/nchs/fastats/ (d) National Patient Safety Foundation. Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human. Boston, MA: National Patient Safety Foundation; 2015. Available at: http://www.npsf.org/free-from-harm.

Situation: I am (name), (X) nurse on ward (X) I am calling about (patient X). I am calling because ... I am concerned that ... (eg blood pressure is low/high, pulse is XX, temperature is XX, Early Warning Score is XX) **Background:** Patient (X) was admitted on (XX date) with ... (eg MI/chest infection) They have had (X operation/procedure/investigation) Patient (X)'s condition has changed in the last (XX mins) Their last set of observations were (XX) Patient (X)'s normal condition is ... (eg alert/drowsy/confused, pain free) **Assessment:** I think the problem is (XXX) And I have ... (eg given O₂/analgesia, stopped the infusion) I am not sure what the problem is but patient (X) is deteriorating

Recommendation:

I need you to ...

Come to see the patient in the next (XX mins)

I don't know what is wrong but I am worried

ANL

Is there anything I need to do in the meantime?

(eg stop the fluid/repeat the observations)

TEACH-BACK C-U-S (Concerned –Uncomfortable –Safety)



Ι	Illness Severity	Stable, "watcher," unstable
P	Patient Summary	 Summary statement Events leading up to admission Hospital course Ongoing assessment Plan
A	Action List	To do listTime line and ownership
S	Situation Awareness and Contingency Planning	 Know what's going on Plan for what might happen
S	Synthesis by Receiver	 Receiver summarizes what was heard Asks questions Restates key action/to do items

CONCLUSION -PART-I

TO REMEMBER.....

- Human error is inevitable
- Make it easy for people to do the right thing
- Make it hard for people to do the wrong thing
- Stop trying to fix people
- Start trying to fix systems
- Work on changing the culture

PART-II

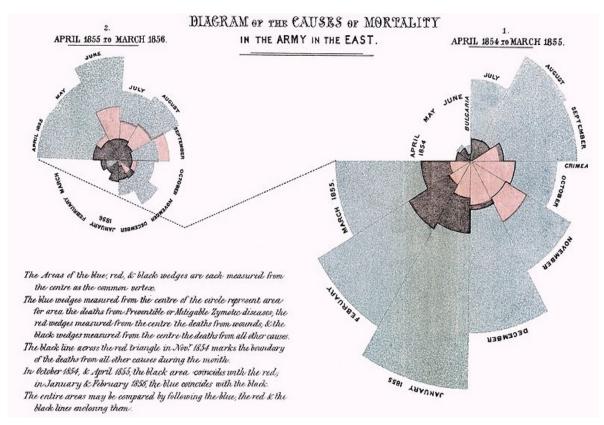
Where the story of QI begins...



"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm" (Nightingale)

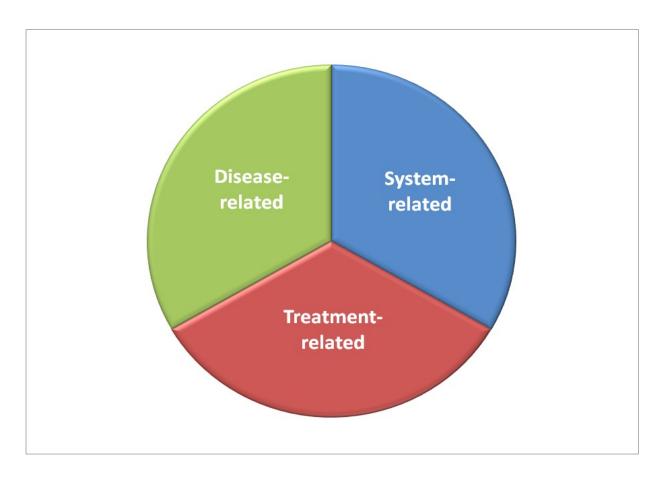
Florence Nightingale (1820-1910)

"Her statistics were more than a study; they were indeed her religion To understand God's thoughts, she held we must study statistics, for these are the measure of his purpose" (Karl Pearson, 1924)

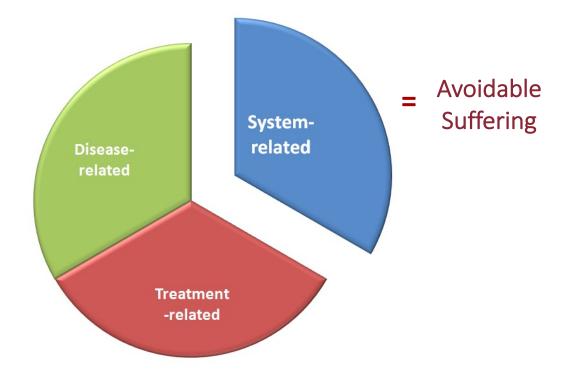


Crimean War – battlefield findings

QI –PATIENT PERSPECTIVE.....



3 Forms of Suffering

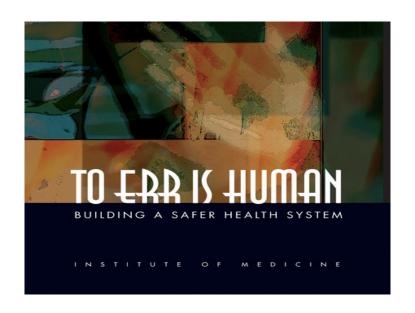


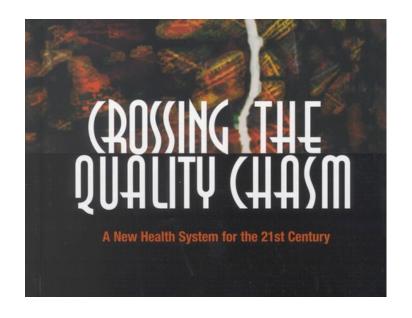
Healthcare is defined as a service....

Don't Harm Me.

Heal Me.

Be Nice to Me.





What is quality?

STEEEP:

- Safe
- Timely
- Effective
- Efficient
- Equitable
- Patient-centred

Research on quality: completely different

Quality assurance: passing the bar

Quality improvement: shifting the curve



Source: Rehn and Krüger, 2014

The Three Faces of Performance Measurement

Aspect	Improvement	Accountability	Research
		(Judgement)	
<u>Aim</u>	Improvement of care (efficiency & effectiveness)	Comparison, choice, reassurance, motivation for change	New knowledge (efficacy)
Methods: • Test Observability	Test observable	No test, evaluate current performance	Test blinded or controlled
• Bias	Accept consistent bias	Measure and adjust to reduce bias	Design to eliminate bias
• Data	"Just enough" data, small sequential samples	Obtain 100% of available, relevant data	"Just in case" data
 Flexibility of Hypothesis 	Flexible hypotheses, changes as learning takes place	No hypothesis	Fixed hypothesis (null hypothesis)
Testing Strategy	Sequential tests	No tests	One large test
Determining if a change is an improvement	Analytic Statistics (statistical process control) Run & Control charts	No change focus (maybe compute a percent change or rank order the results)	Enumerative Statistics (t-test, F-test, chi square, p-values)
Confidentiality of the data	Data used only by those involved with improvement	Data available for public consumption and review	Research subjects' identities protected

Adapted from: Lief Solberg, Gordon Mosser and Sharon McDonald, *Journal on Quality Improvement*, vol. 23, no. 3, (March 1997), 135-147.

DIAGNOSTIC PROCESS

QUALITY IMPROVEMENT

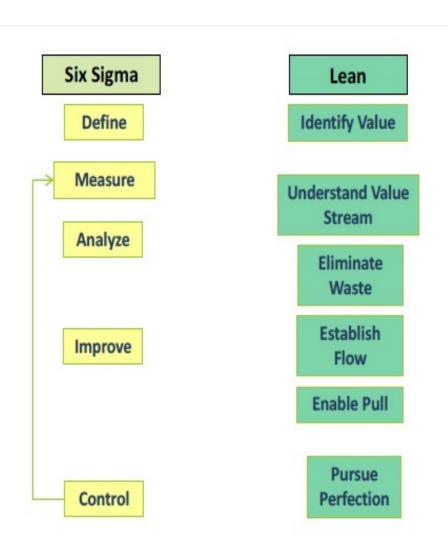
Presenting complaint	System/process issue		
History & physical	Root-cause analysis		
Diagnostic tests	Data gathering		
Diagnosis	System diagnosis		
Treatment	PDSA cycles		
Follow-up	Sustainability		

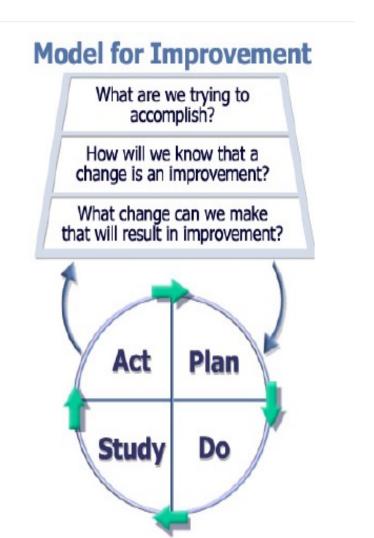
RESEARCH

QUALITY IMPROVEMENT

Focus on 'what'	Focus on 'how'
Clinical decisions	Processes of care
On topic of effectiveness	On 6 domains of quality
Fixed hypothesis	Evolving hypotheses with PDSA cycles
Ideal conditions, blinded, unbiased	Real-world conditions, open/transparent, accepting bias
Spread at population-level	Apply local solutions

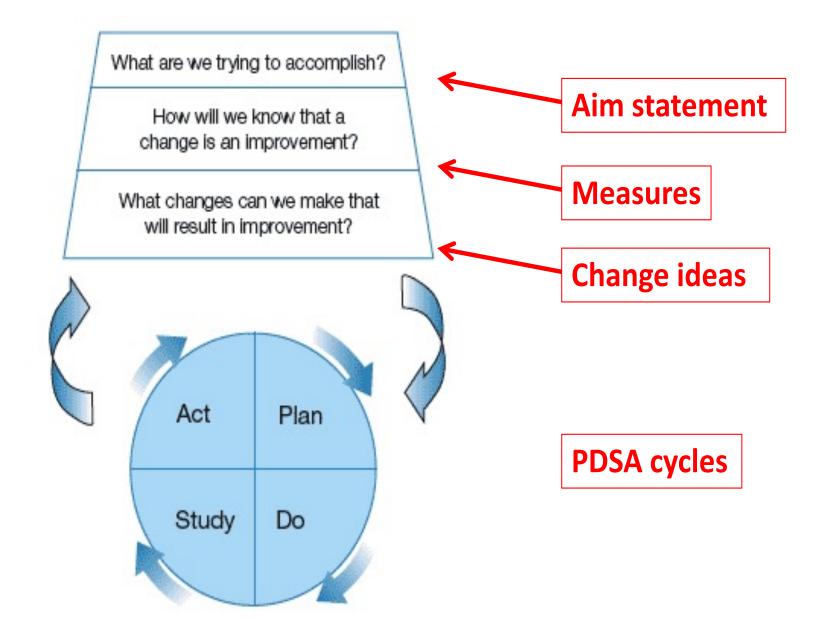
WHAT ARE QI METHODOLOGIES?







MODEL FOR IMPROVEMENT



SMART AIM STATEMENT

- SPECIFIC
- MEASURABLE
- ACTIONABLE
- REALISTIC
- TIMELY

- 1.WHAT?2.BY HOW MUCH?3.WHEN?
- 1. I want to improve the number of patients seen virtually in Hematology clinic.
- 2. I want to improve the number of patients seen virtually in Hematology clinic from the current 30% to 50% by March 2023.

"Some is not a number, soon is not a time."

- Don Berwick, December 2004, at launch of 100,000 Lives Campaign

MEASUREMENTS

OUTCOME MEASURE:

- Voice of the Customer
- Impact on Patients / staff /Population

PROCESS MEASURE:

- Voice of the System
- What is being done while receiving / providing care

BALANCING MEASURE:

- What else changed?
- Unintended consequences

OUTCOME MEASURE:

Improvement in virtual clinic numbers by 50%.

PROCESS MEASURE:

- No. of appointments booked
- No. of patients contacted prior to appointment

BALANCING MEASURE:

- -Time spent for each virtual care evaluation
- -Lab tests ordered prior and post appointment

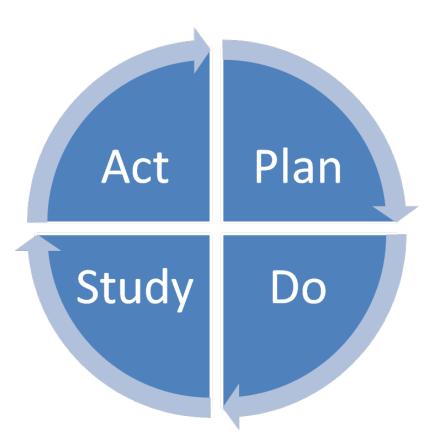
PDSA CYCLE

P: Formulating a hypothesis

D: Collecting data to test this hypothesis

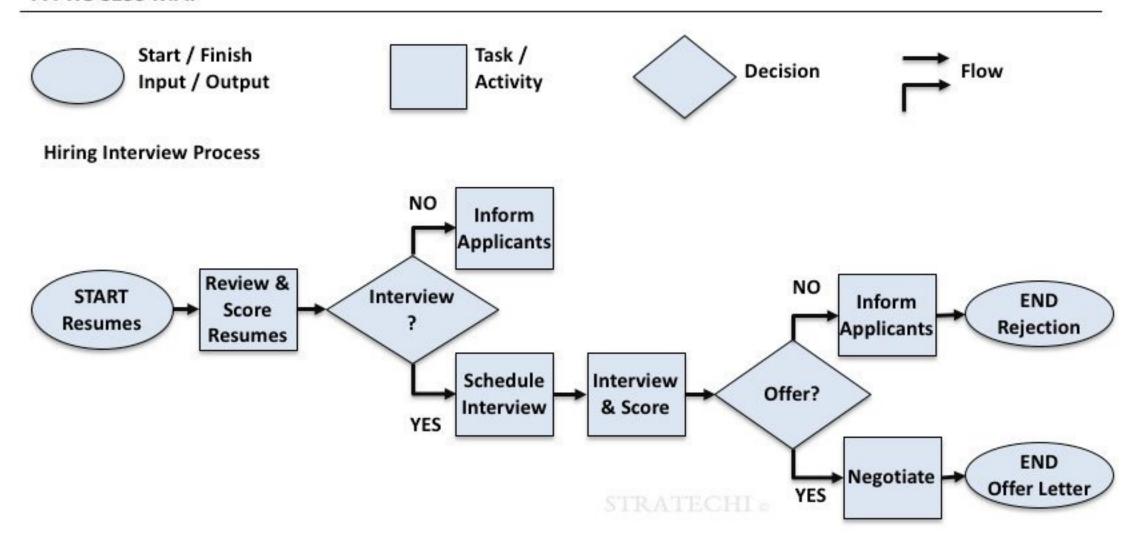
S: Analyze and interpret results

• A: Make inferences to iterate the hypothesis

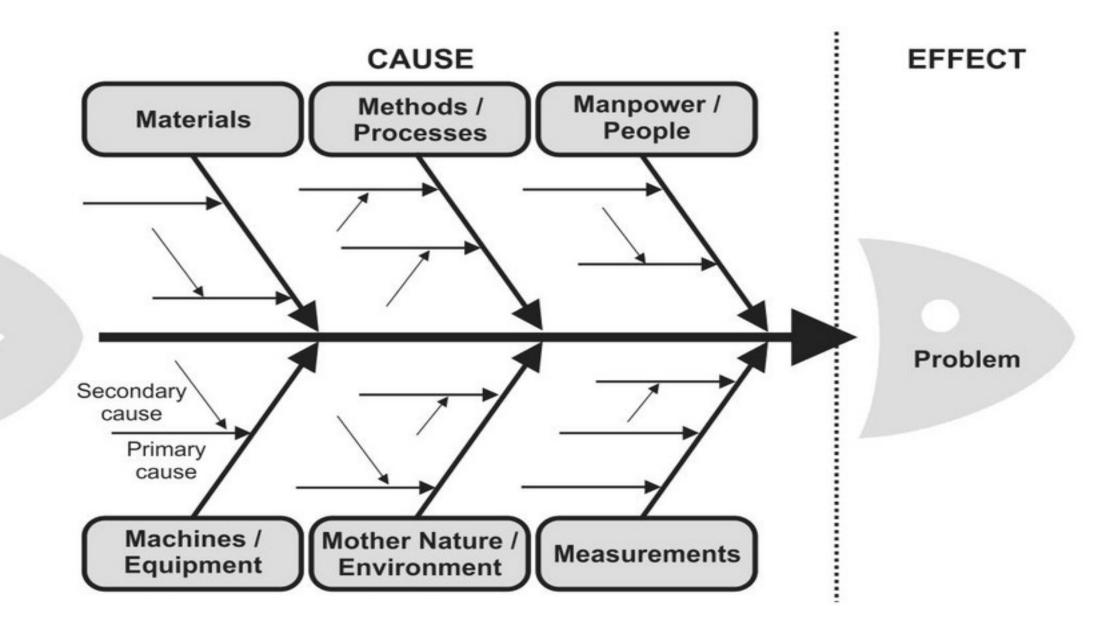


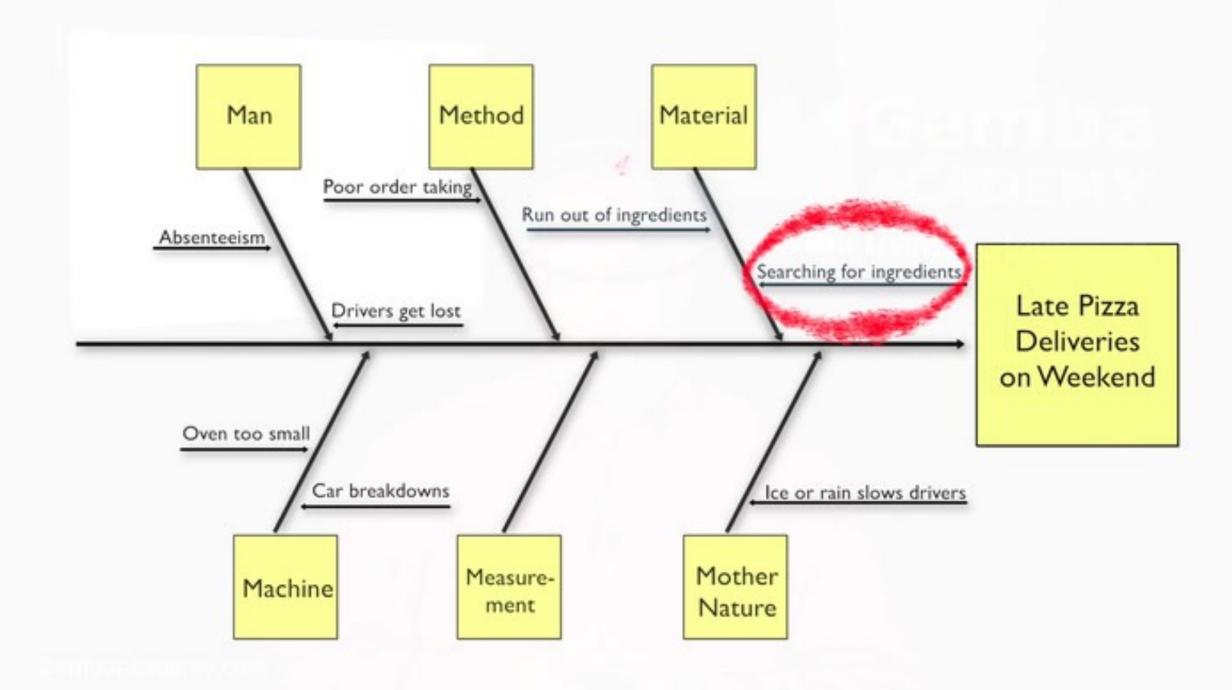
PROCESS MAP

A PROCESS MAP



FISHBONE (ISHIKAWA) DIAGRAM

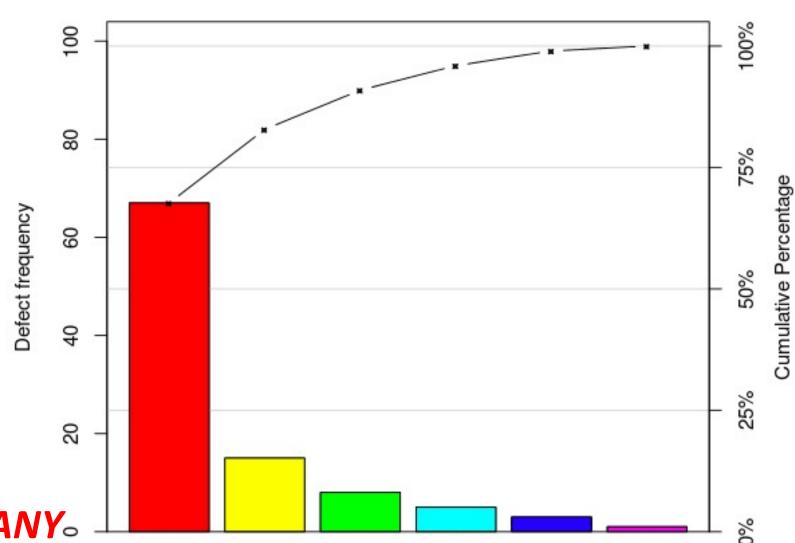




PARETO DIAGRAM

Principle:

Approximately
 80% of the
 effects come
 from 20% of the
 causes



VITAL FEW VS. TRIVIAL MANY.

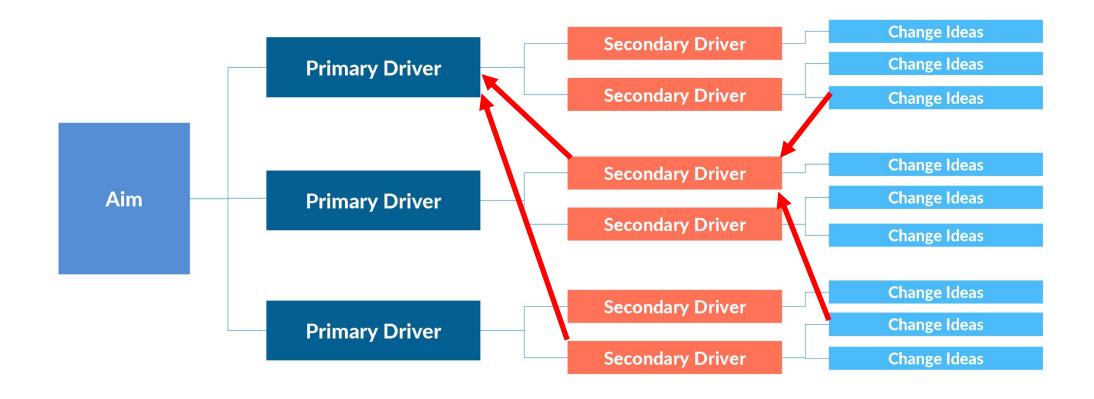
DRIVER DIAGRAM

Aim: In order to achieve this aim...

Primary drivers: ...we need to ensure...

Secondary drivers: ...which requires...

Changes: ...ideas to ensure it happens



DATA AND MEASUREMENT IN QI

Enumerative Vs. Analytic

Types of Chart

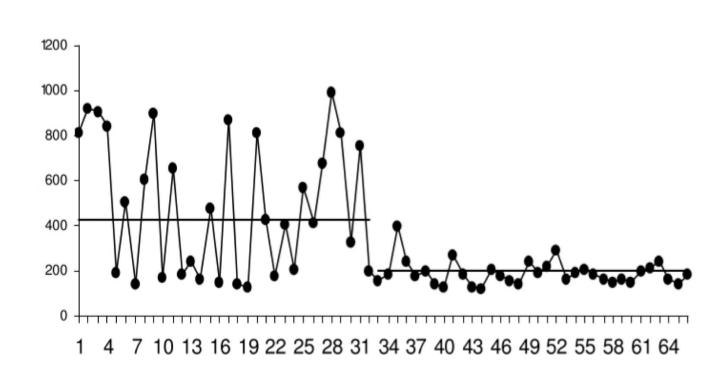
RUN Chart

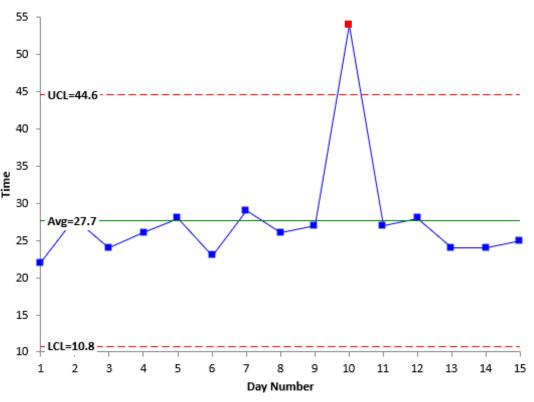
CONTROL Chart

- Basic Principles:
 - Data Over Time
 - To differentiate Common Cause ('Noise') Vs. Special Cause ('Signal')
 - Analysis before and after intervention

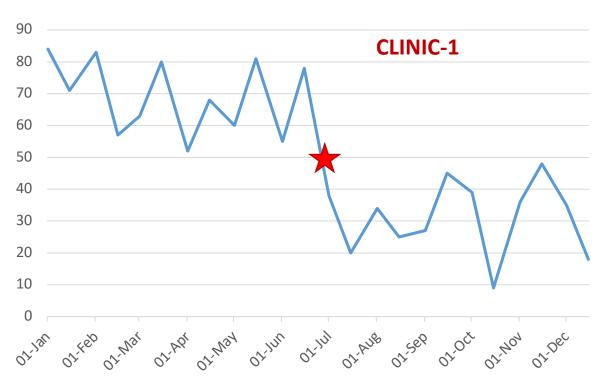
RUN CHART

CONTROL CHART





WAIT TIME TO SEE THE PHYSICIAN (IN MINUTES)	CLINIC 1	CLINIC 2	CLINIC 3
	50	55	45
	49	52	-5
	60	58	58
	63	57	52
	57	56	60
	52	53	54
	55	58	59
	••	••	••
	••	••	••
MEAN BEFORE	55	55	55
SD	10	10	10
MEAN AFTER	33	33	33
SD	10	10	10
P value	< 0.01	< 0.01	< 0.01
MEDIAN	52	52	52



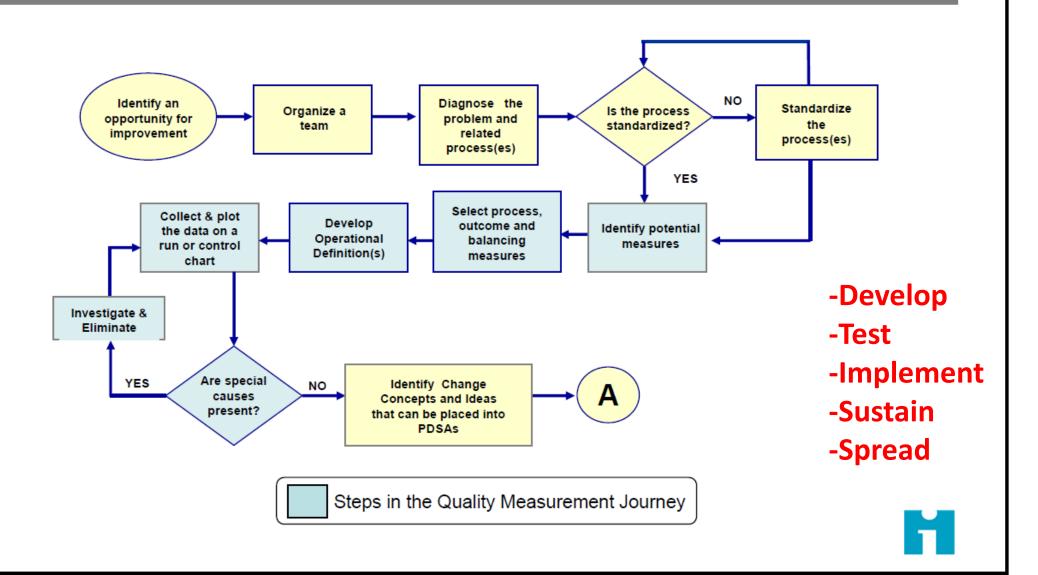




The Quality Improvement Journey

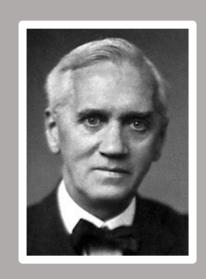
Source: Carey, R. and Lloyd, R. Measuring Quality Improvement in Healthcare: A Guide to Statistical Process Control Applications.

ASQ Press, Milwaukee, WI, 2001.



THE STORY OF PENICILLIN.....

The Nobel Prize for Medicine was awarded in 1945 to:



Sir Alexander Fleming

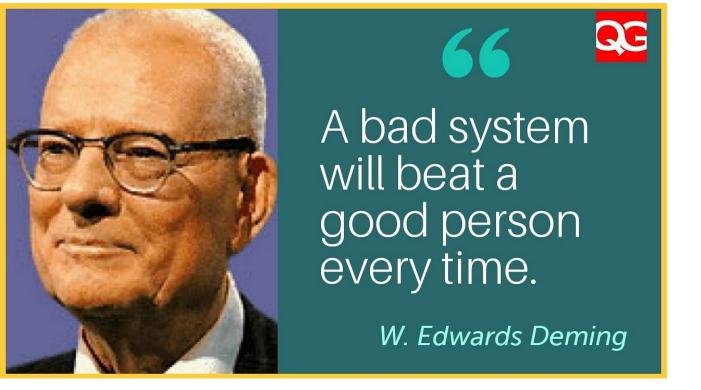


Ernst B. Chain



Sir Howard Florey

- Sir Henry Harris at the Florey Centenary lecture (1998):
 - "Without Fleming, no Chain;
 - without Chain, no Florey;
 - without Florey, no Heatley;
 - without Heatley, no penicillin."
- In other words:
 - Without Fleming, no innovation;
 - without Chain and Florey, no <u>testing</u>;
 - without Heatley, no wide scale use of penicillin.



Quality is more important than quantity. One home run is much better than two doubles.

Steve Jobs

Improvement Tip: Take the Journey to "Jiseki"

Stage ONE: Data are Wrong

Stage TWO: Data are Right; But it is not a Problem

• Stage THREE: Data are Right; there is a Problem; But it is not my Problem. Taseki

• Stage FOUR: Data are Right; there is a Problem; But it is my Problem.

Jiseki

CONCLUSION — PART-II

- Start Small
- Have an Aim, Measure and Ideas
- Run multiple PDSA cycle
- 1st TEST and then Implement

REMEMBER: Every System is Perfectly Designed To Get The Results It Gets!

THANK YOU

