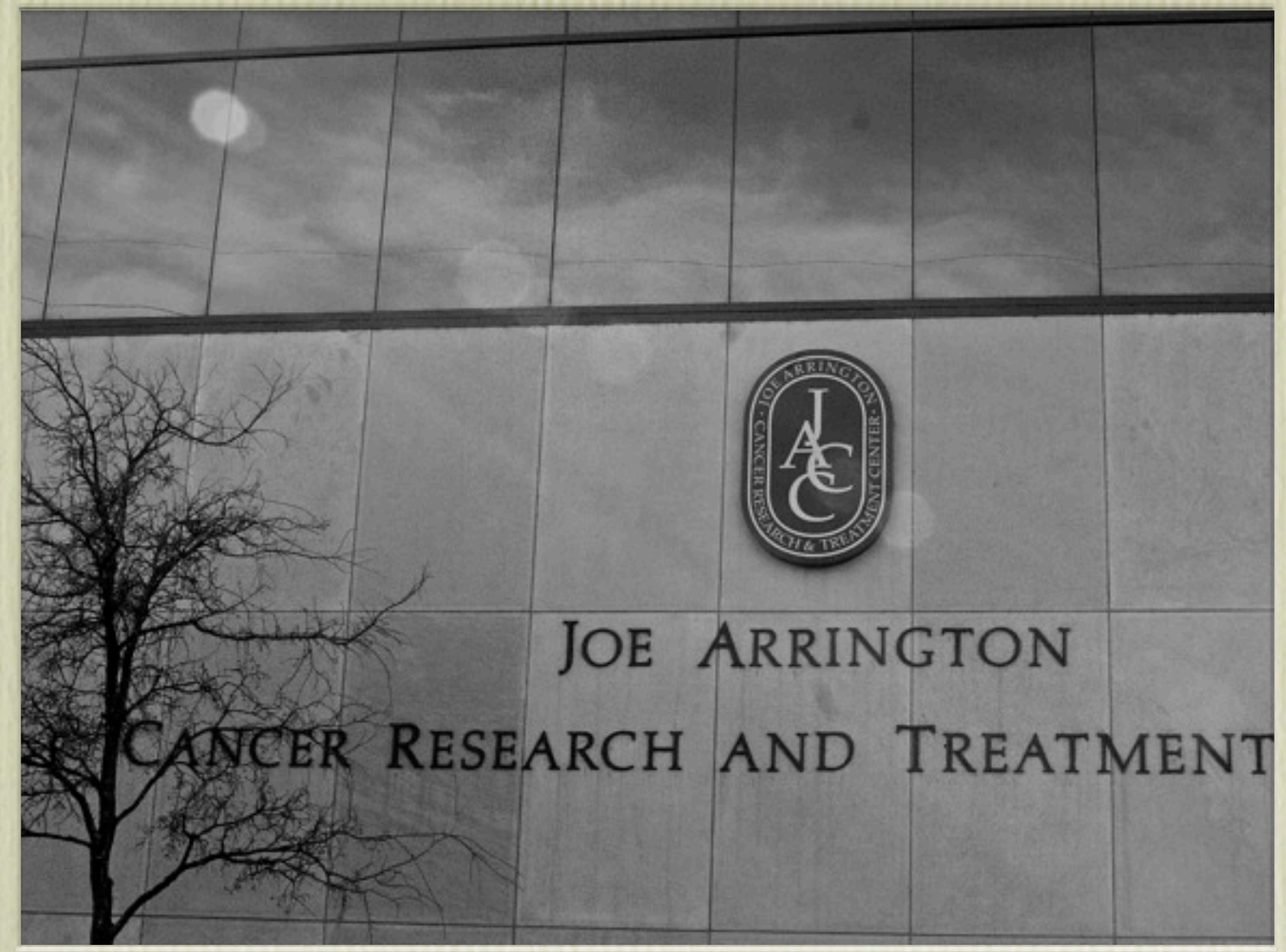


Patient Safety and Quality Management

Patient Safety

- Why Quality Management, and Patient Safety
- How can be Implemented
- Here at CMC?

To Err is Human

Why?

In 1994 BL, a popular Boston Globe health columnist, had Breast Ca. and was scheduled to receive high dose cyclophosphamide 4 g/sq m over 4 days, instead she got 4 g/sq m once a day for 4 days, she got a four fold dose and died a month later.

How?

Lack of Standardization and Ambiguity

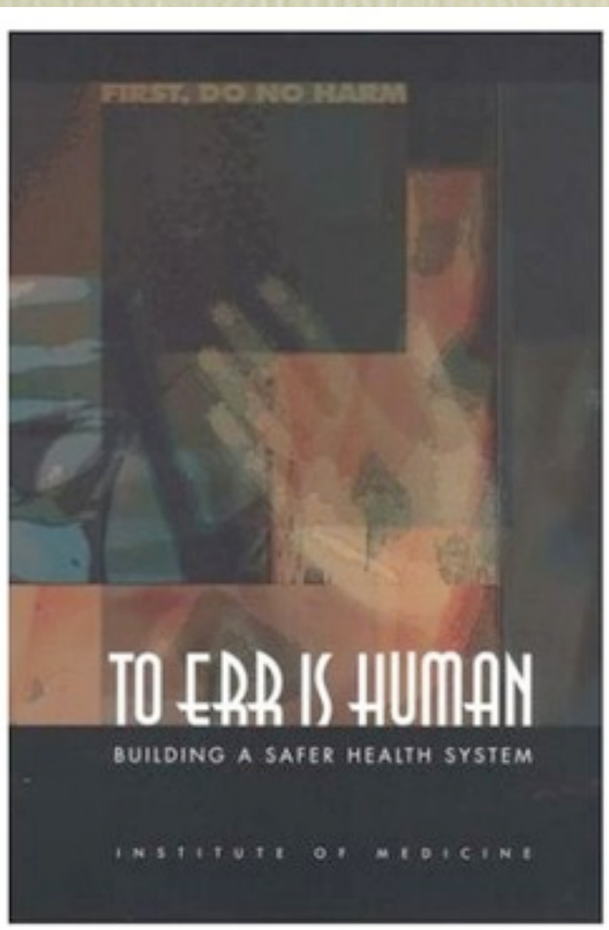
Where?

Dana-Farber Cancer Institute

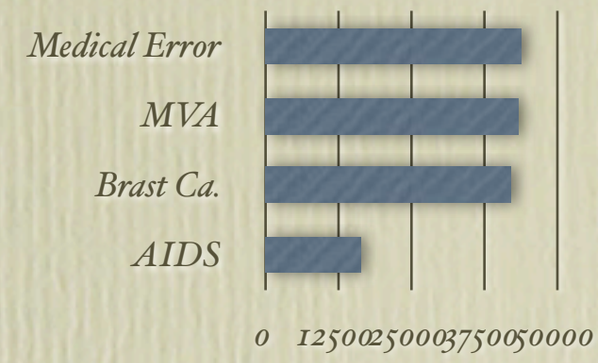
To Err is Human

- To Err is Human: Building a Safer Health Care System. Published by IOM in 1999.

- Patient Safety: A Critical Component of Quality



To Err is Human

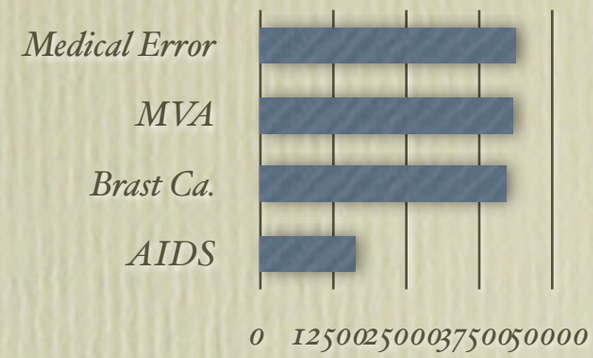


- Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.

- In Colorado and Utah hospitals, 6.6 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals.

- In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.

To Err is Human:Stats



- When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, this results imply that at least 44,000 Americans die each year as a result of medical errors.

- The results of the New York Study suggest the number may be as high as 98,000.

- Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th-leading cause of death.

To Err is Human

- More people die in a given year as a result of **medical errors (44,000 to 98,000)** than from:

motor vehicle accidents (43,458),

breast cancer (42,297),

or AIDS (16,516).

To Err is Human: Cost

- Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (are estimated to be between $17 billion and $29 billion, of which health care costs represent over one-half.

- In terms of lives lost, patient safety is as important an issue as worker safety.

- Every year, over 6,000 Americans die from workplace injuries. Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.

To Err is Human:Human Cost

- Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly.

- One recent study conducted at two prestigious teaching hospitals, found that about two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital.

- If these findings are generalizable: $2 billion for the nation as a whole.

To Err is Human

- These figures offer only a very modest estimate of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total cost.

- Outpatient surgical centers, physician offices and clinics serve thousands of patients daily.

To Err is Human:Emotional Cost

- Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes.

- But not all the costs can be directly measured. Errors are also costly in terms of **loss of trust in the system by patients** and **diminished satisfaction by both patients and health professionals**.

To Err is Human:Emotional Cost

- Patients who experience a longer hospital stay or disability as a result of errors pay with **physical and psychological discomfort**.

- Health care professionals pay with **loss of morale and frustration** at not being able to provide the best care possible.

- Employers and society, in general, pay in terms of **lost worker productivity, reduced school attendance** by children**,** and **lower levels of population health status**.

- **Yet silence has surround this issue.**

To Err is Human:Awareness

- For the most part, consumers believe they are protected.
- Media coverage has been limited to reporting of anecdotal cases.
- Licensure and accreditation confer, in the eyes of the public, a “Good Housekeeping Seal of Approval.”
- Licensing and accreditation processes have focused only limited attention on the issue, and even these minimal efforts have confronted some **resistance** from health care organizations and providers.

To Err is Human: Why?

- The decentralized and fragmented nature of the health care delivery system (some would say "**non-system**") also contributes to unsafe conditions for patients, and serves as an impediment to efforts to improve safety.

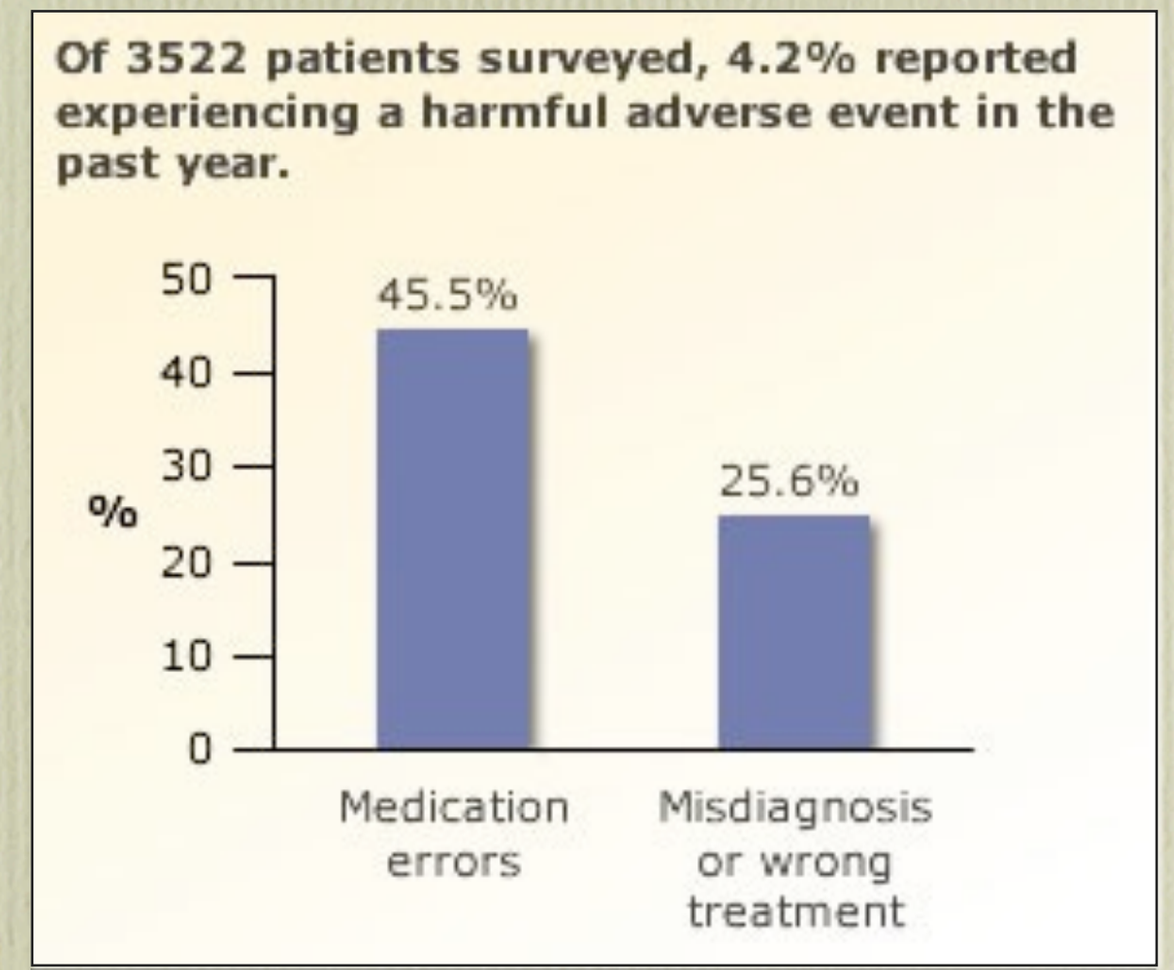
- **Unsafe care** is one of the prices we pay for not having organized systems of care with clear lines of accountability.

To Err is Human

- Lastly, the context in which health care is purchased further exacerbates these problems. Group purchasers have made, in the past, few demands for improvements in safety.

- Most third party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality. This is about to change.

That was in 1998, what about 2008?



Adams RJ, Tucker G, Price K, et al. Self-reported adverse events in health care that cause harm: a population-based survey. Med J Aust. 2009;190:484-488

To Err is Human

- Medicare will deny payments for DRGs that were suppose not to happen: “never events”

  Wrong side surgery

  Pressure ulcers

  ABO incompatible blood transfusions

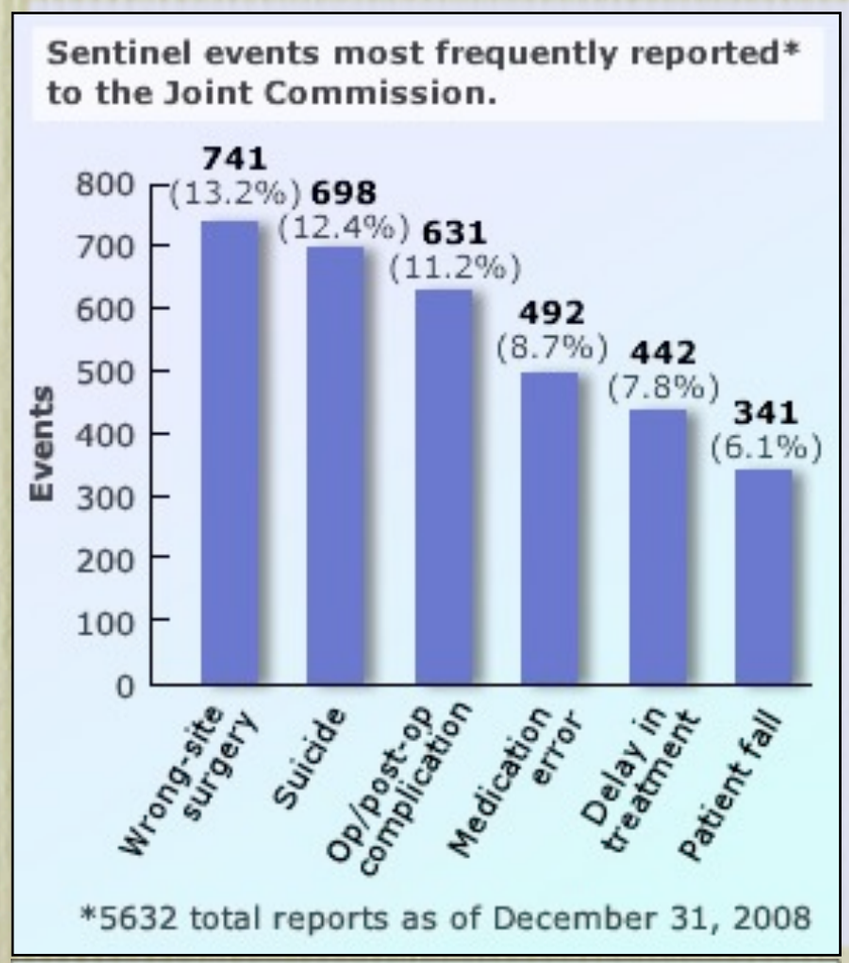
- and, not yet but expanding to

  Catheter related UTI

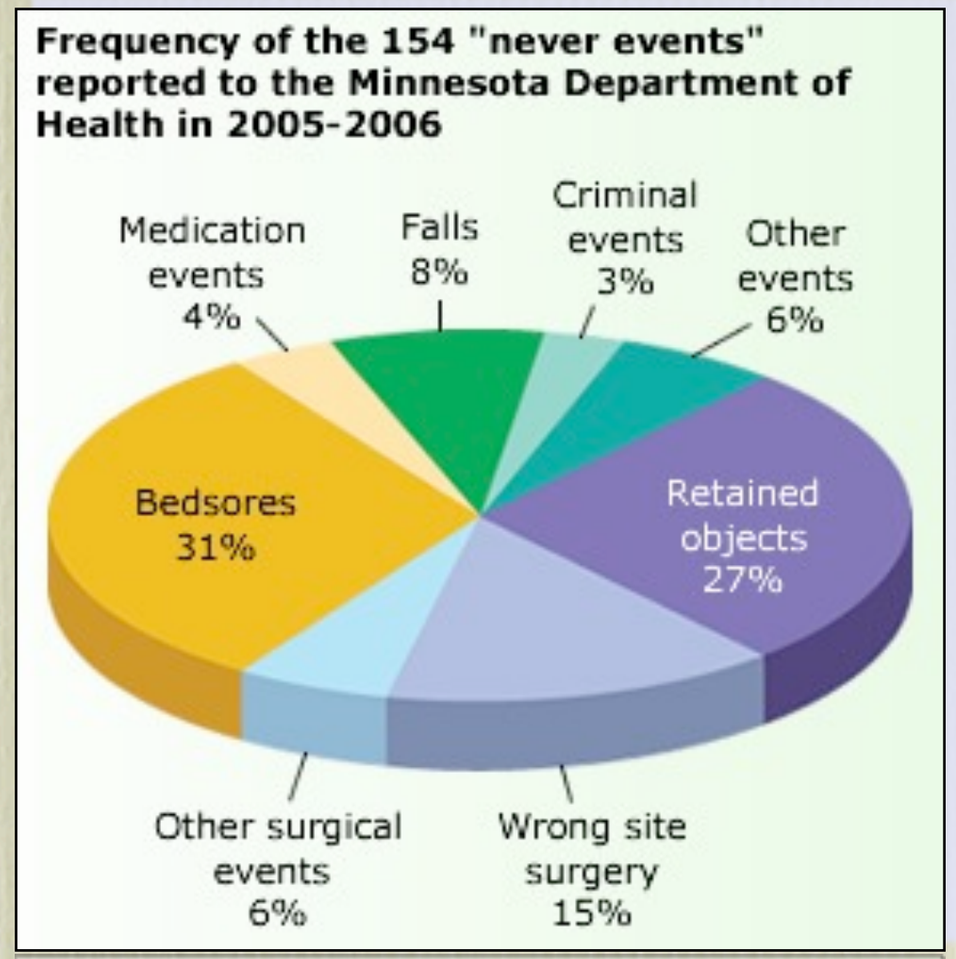
  Ventilator Associated Pneumonia

  Inpatient Falls

Sentinel Events / Never Events

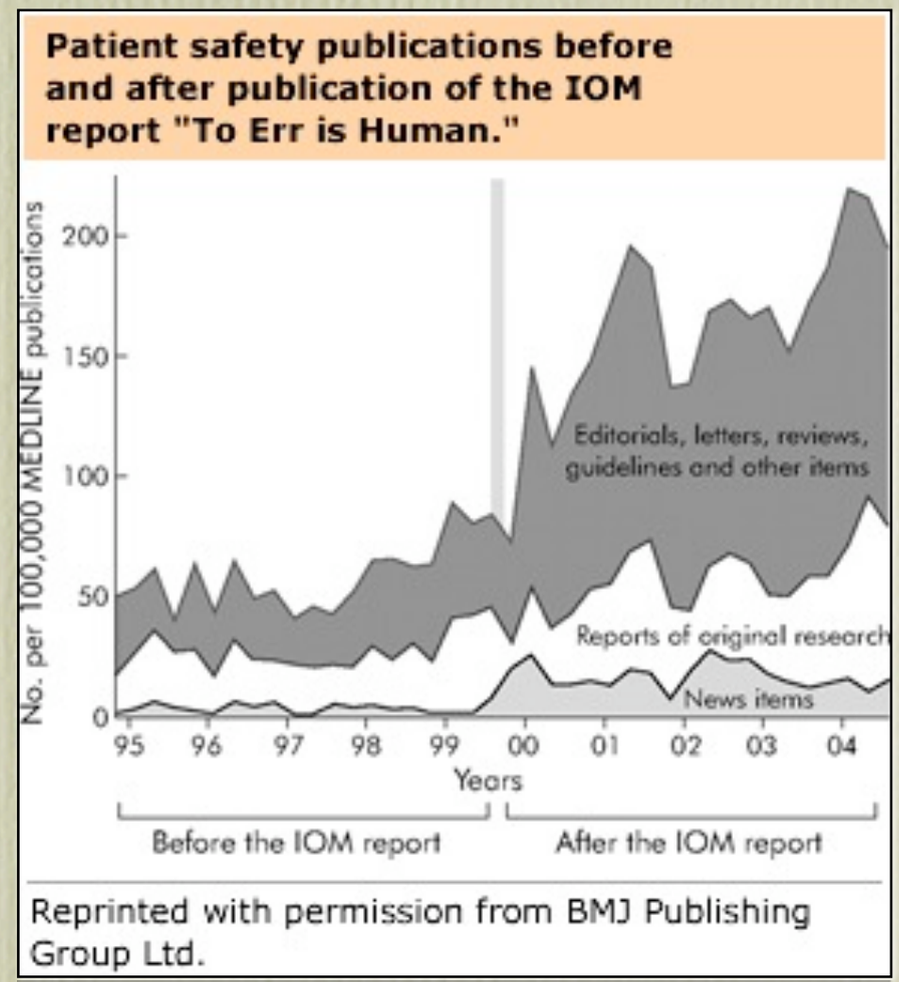


Sentinel Event Statistics. December 31, 2008. The Joint Commission Web site



Minnesota Department of Health; January 2007. Available at: http://www.health.state.mn.us/patientsafety/publications/consumerguide.pdf.

Impact of To Err is Human



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Stelfox HT, Palmisani S, Scurlock C, Orav EJ, Bates DW. The "To Err is Human" report and the patient safety literature. Qual Saf Health Care. 2006;15:174-178

To Err is Human

- The status quo is not acceptable and cannot be tolerated any longer. Despite the **cost** pressures, liability constraints, **resistance** to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort.

- "First do no harm"

First Do Not Harm

In rather, large, complex problems, like this, the approach cannot focus on a single solution since there is no “magic bullet”

The approach will require thoughtful, multifaceted responses

- **Safety** is defined as freedom from accidental injury
- **Error** is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

First Do Not Harm

- Errors depend on two kinds of failures:

  1. the correct action does not proceed as intended (an error of execution) or

  2. the original intended action is not correct (an error of planning).

- Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

First Do Not Harm

- **An adverse event** is an injury resulting from a medical intervention, in other words, it is not due to the underlying condition of the patient. (i.e.: toxicity's from chemotherapy: Fatigue, Nausea, Anemia, Neutropenia, Extravasation)

- While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). (i.e., Fatigue, Nausea, Anemia, Neutropenia)

- Errors that do result in injury are sometimes called preventable adverse events (Nausea/Vomiting [volume contraction] due to lack of indicated anti nausea premeds, neutropenia and fever [hospitalization] due to lack of indicated GCSF)

- Now, not all errors result in harm.

Adverse Event

- For example, if a patient has surgery and dies from pneumonia he or she got post operatively, it is an adverse event.

- If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution).

- But the analysis may conclude that no error occurred and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event) [neutropenia, fever and hospitalization in spite of GCSF and prophylactic antibiotics]

Adverse Event

- Because much can be learned from the analysis of errors: All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future.

- Errors (and near misses) that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

- Preventing errors means designing the health care system at all levels to make it safer.

Adverse Event

- Building safety into processes of care (blunt end) is a more effective way to reduce errors than blaming individuals (sharp end)

- improving processes is the only way to improve quality.

- **The focus must shift** from blaming individuals for past errors to a focus on **preventing future errors by designing safety into the system**.

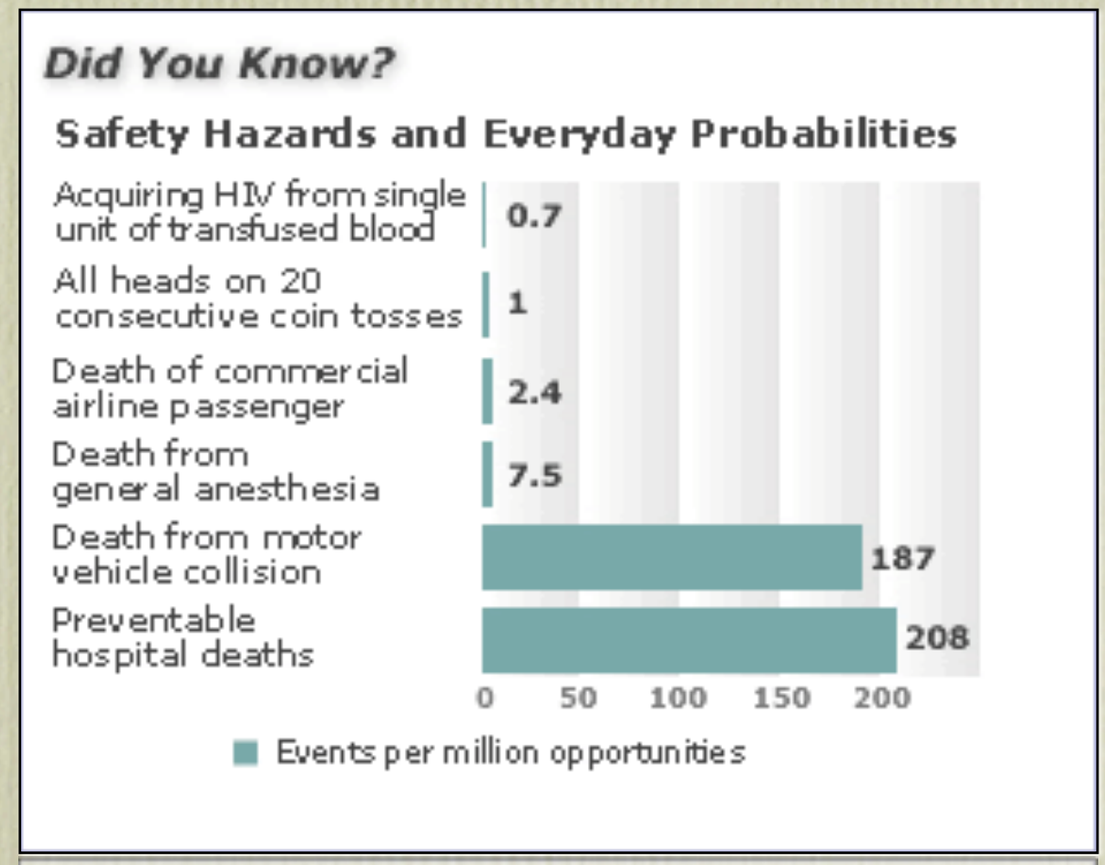
- This does not mean that individuals can be careless.

- Aviation has focused extensively on building safe systems: Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century.

- n 1998, there were no deaths in the United States in commercial aviation.

- Although health care may never achieve aviation's impressive record, there is clearly room for improvement.

Did you know?



1. Transfusion—Allain JP. Transfusion risks
Transfus Clin Biol. 2003;10:1-5. [go to pu

2. Coin flips—Probability = 0.5 raised to th

3. Airline—From 1992-2002 annual numbe
US commercial flights ranged from zero to
million passenger enplanements. The med
per million, with an inter-quartile range of
www.ntsb.gov/aviation/Table3.htm].

4. Anesthesia—Lagasse RS. Anesthesia sa
review of the published literature and anal
Anesthesiology. 2002;97:1609-1617. [go

5. Automobile—Approximately 42,000 dea
motor vehicles; approximately 225 million
United States. Since 225 million is reasona
population of the United States, the morta
motor vehicles does not change substantia
citizens as the denominator. Note that we
denominator rather than vehicle miles trav
ratio analogous to mortality rates in health
per numbers of patient admissions or oper
days. Similarly, the aviation statistics pres
passenger enplanements, not hours of fligh

Patient Safety

- Safety is a critical first step in improving quality of care. Factors needed inside health care organizations include:

1. Strong leadership for safety,

2. An organizational culture that encourages recognition and learning from errors, and

3. An effective patient safety program.

Nationwide Effort

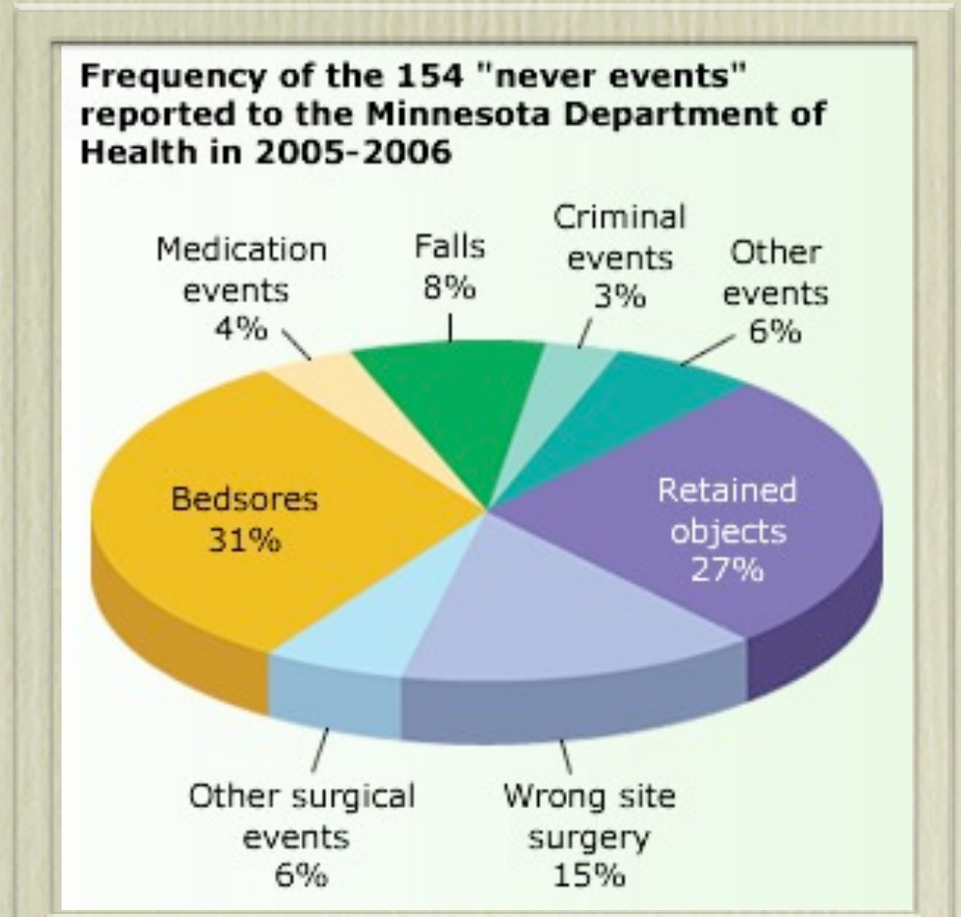
- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety:

  • identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;

  • raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and

Nationwide

But now, reporting is becoming **mandatory**, on specific cases that involve serious harm or death (**never events, sentinel event**), this will result in fines or penalties relative to the specific case, and



Patient Safety at “home”

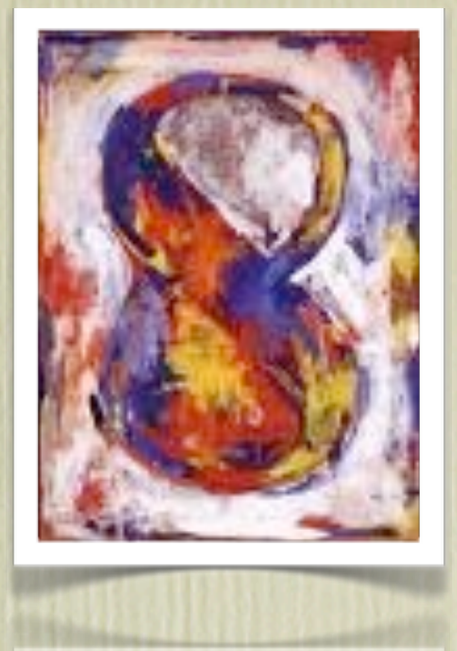
- Creating **safety systems inside health care organizations** This level is the ultimate target of all the recommendations.

- To create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance: **Safety and Quality Management Program**.

IOM To Err is Human: **RECOMMENDATION**

- Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility.

IOM To Err is Human: **RECOMMENDATION**



- 8.1 Patient safety programs should

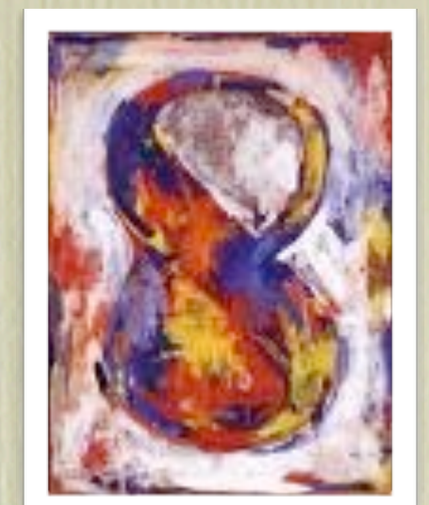
  • provide strong, clear and visible attention to safety;

  • implement non-punitive systems for reporting and analyzing errors within their organizations;

  • incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and

  • establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.

IOM To Err is Human: **RECOMMENDATION**



- 8.2 Health care organizations should implement proven medication safety practices.

Patient Safety: A Critical Component of Quality

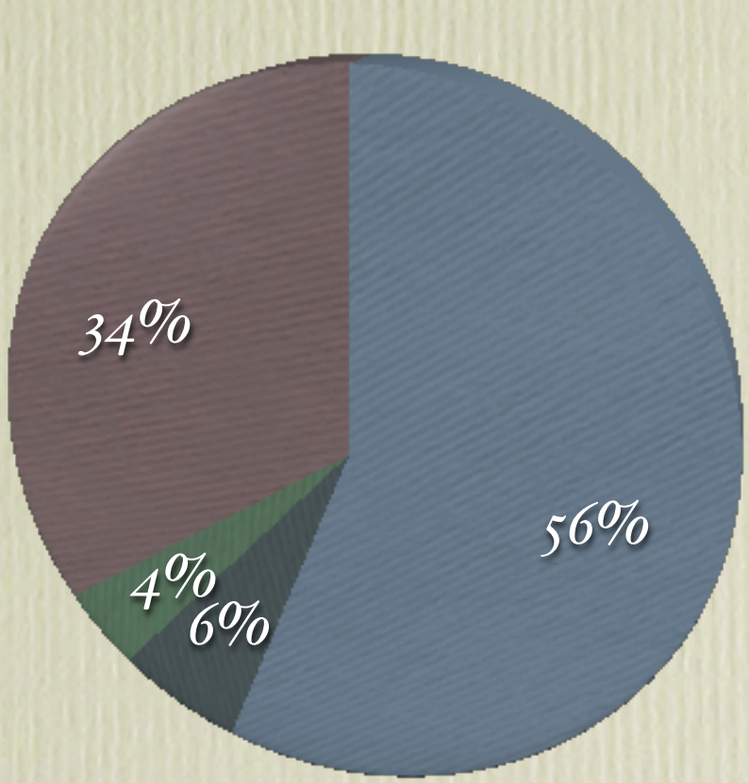
- With adequate leadership, attention and resources, improvements can be made. It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives and meet the challenges ahead.

- To Err Is Human asserts that the problem is not bad people in health care--it is that good people are working in bad systems that need to be made safer

Medication Errors

by stage of the medication process

- Ordering
- Transcribing
- Dispensing
- Administration



Top  barriers to implementing patient safety system

Top seven barriers to implementing patient safety systems

1. Competing priorities for scarce resources in a system where patient safety is not considered a top priority.
2. Lack of resources: inadequate staffing and work overloads.
3. Availability and cost of patient safety technology.
4. Resistance to change (the assumption that providers are already providing safe care).
5. Culture of blame (current healthcare culture is punitive in nature).
6. Lack of senior leadership understanding of and involvement with patient safety issues.
7. Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."

IOM's 6 aims for quality health care system

- Health care must be Safe
- Health care must be Effective
- Health care must be Patient Centered
- Health care must be Timely
- Health care must be Efficient
- Health care must be Equitable

Glossary

- Sentinel Event
- Mistake and Error (of commission or omission)
- Slips (or lapses)
- Near Miss
- Just Culture
- Latent Error (accident waiting to happen)

Glossary

- Authority Gradient
- Blunt end versus Sharp end

Patient Safety and Quality Management (QM): Purpose

- To assess and continuously improve the processes and outcomes of transplantation through an integrated interdisciplinary team representing the

1. Clinical,

2. Collection, and

3. Processing Programs

in order to provide the most successful outcome possible for each patient.

QM Core Members

A. **Physicians**: (Program Director – Committee Chairman)

B. **Clinical, Collections and Cellular Therapy Program Directors**

C. **Cellular Therapy Laboratory**

D. **Transplant Coordinators**

E. **Nursing Directors of Inpatient and Outpatient**

F. **Collections Nursing Director**

G. **Infection Control**

H. Subject matter experts as needed (i.e. **Laboratory, Pharmacy, Food and Nutrition, Radiology, Radiation Therapy**)

QM: Scope

Responsibilities

A. Prioritizing and develop **performance measures** with which to assess the process and outcome of collection, processing and therapy (Product CD34+ Cells: 2 Million or more)

B. Establishing processes for data collection and analysis

C. Assessing results of measurement (Goal met or not)

D. Identifying and prioritize **improvement opportunities** (Longer Collection, timing of GCSF dose, Identify poor candidates for Mob)

E. Developing improvement strategies (Timing of GCSF injection)

F. Developing performance measures to determine the efficacy of the change (Audit if Product CD34+ Cells is 2 M or more))

QM: Scope

G. Implementing improvement strategies with time line and assigned responsibilities (Apply new dosing schedule of GCSF)

H. Measuring results of improvement efforts within 4 months of the change

I. Continuing implemented improvement strategy or develop alternatives based on results of measurement

QM: Additional Activities

- Reviewing and discussing (occurrence) variance reports.
- Reviewing audit results and action plans
- Assessing staff education
- Assessing staff competency
- Annual review, revision, and approval of all policies and procedures Ensuring compliance with FACT Standards.

QM: Occurrence Reporting

1. Reporting includes all variances, accidents, errors, significant adverse reactions (preventable or not) and complaints.

2. All occurrence reports are presented to the BMT Quality Management Committee.

3. Should Risk Management deem an occurrence as sentinel event or unanticipated outcome, BMT staff and physicians close to the event participate in the **root cause analysis (RCA) in accordance with CHS policies on sentinel events and unanticipated outcomes**

4. Corrective actions shall be implemented as appropriate and the effectiveness of corrective actions shall be verified.

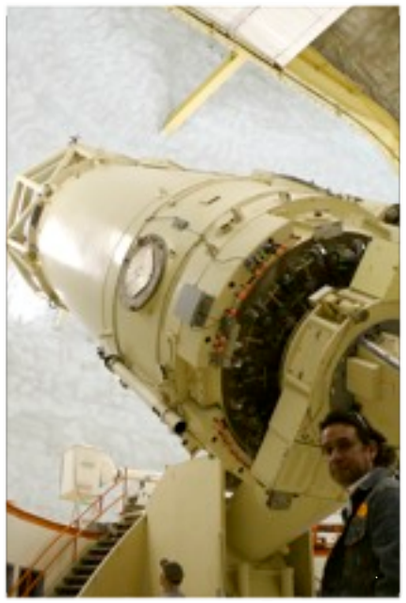
5. When applicable, the event **shall be reported to appropriate regulatory agencies (FDA, CIBMTR)**

QM Infinite Cycle: Performance Measurement / Assessment / Improvement

Improvement Strategy

Change Process:

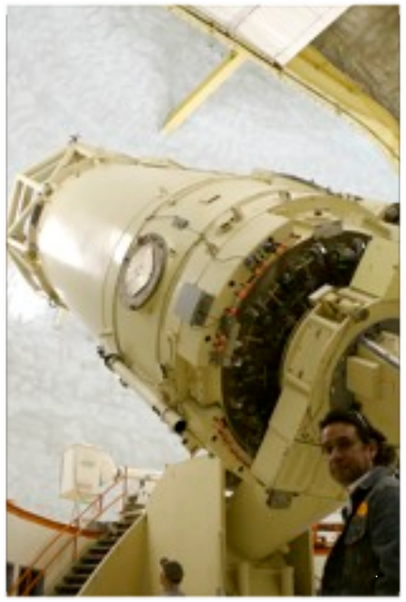
1. A structured mechanism for the management of significant change is used to avoid unintended negative consequences on another area or established process.



QM here at CHS?

ty Management and Patient Safety cannot be established exclusively for a HSCT Program, has to be integrated in an Hematology Oncology Inpatient and Outpatient Service Line, and as part of a Health System basic operation.

Different Parts of QM program are already in operation system wide: Clinical Lab, Blood Bank, Infectious Ds Control, “Credentialing”, and others, but they need to be “connected” “bench marked” “opportunities of improvement” detected, processes modified, audited and analysed.

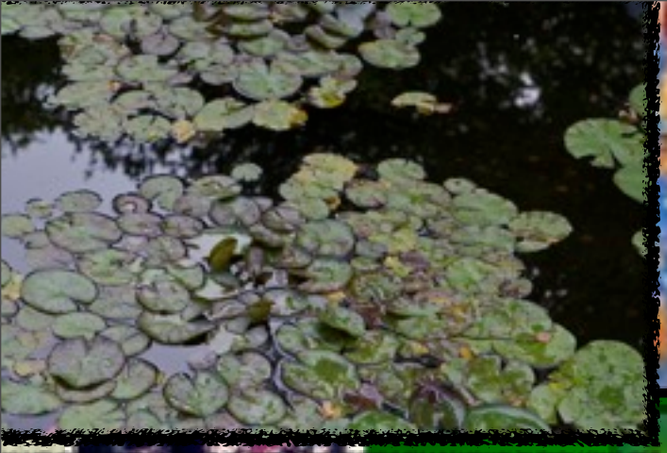


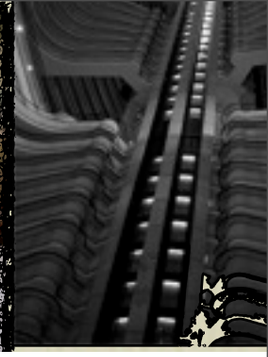
and finally

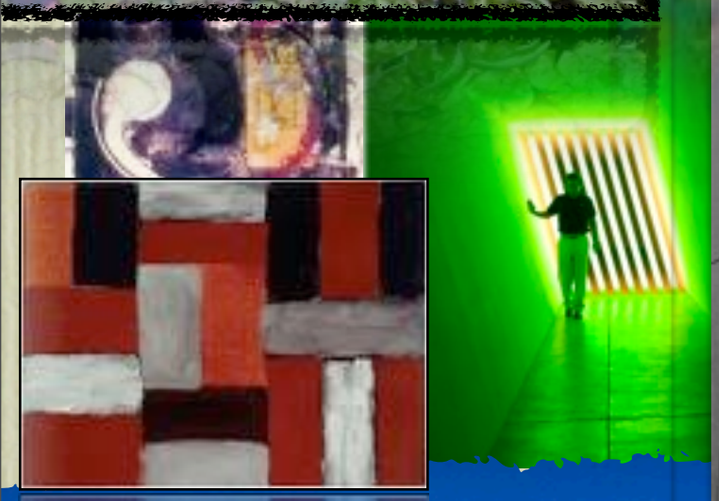
- A good QM/Patient Safety Program must be integrated with an excellent Health Care Professional-Patient Interaction

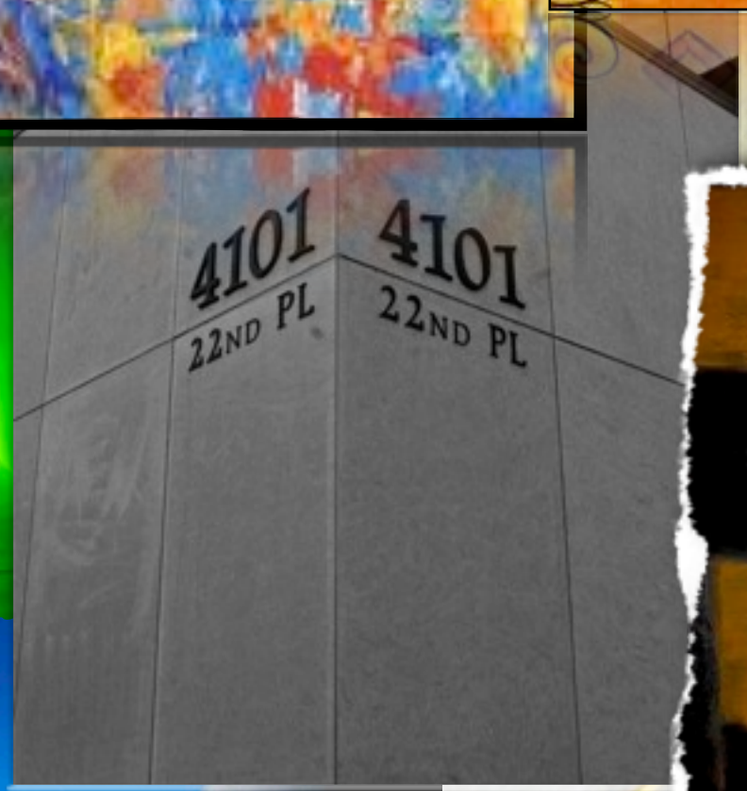
- The perception of quality can be absent if the interaction health care professional-patient is not with courtesy, promptness and professional at all times.

- We need to acquire a uniform reproducible set of skills to consistently convey to the patients the sincere care and quality contained in our day to day operation.





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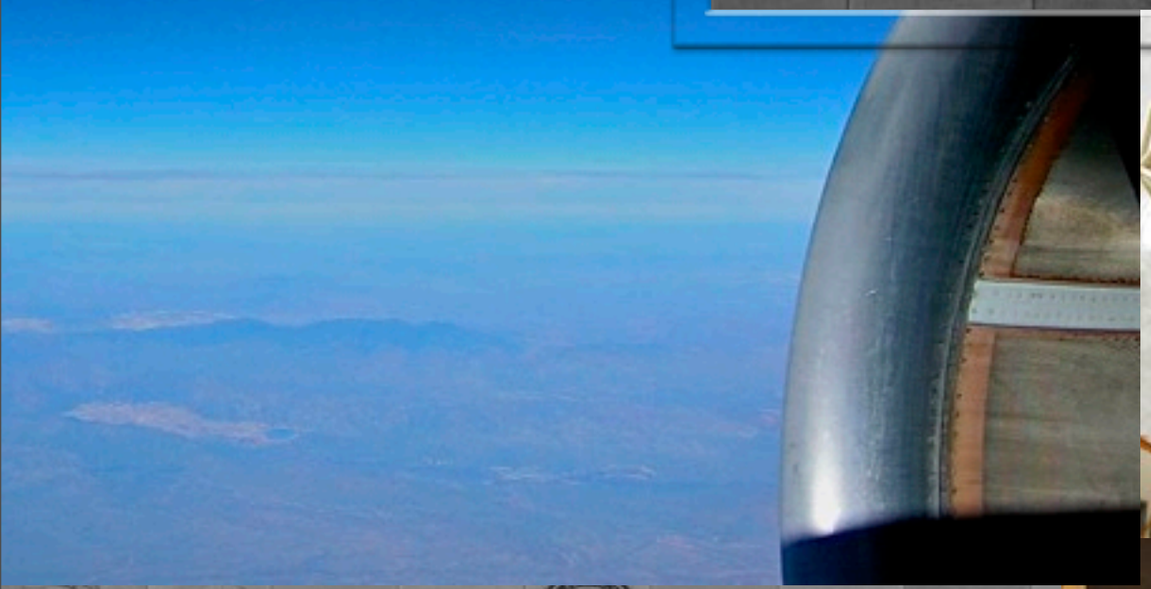


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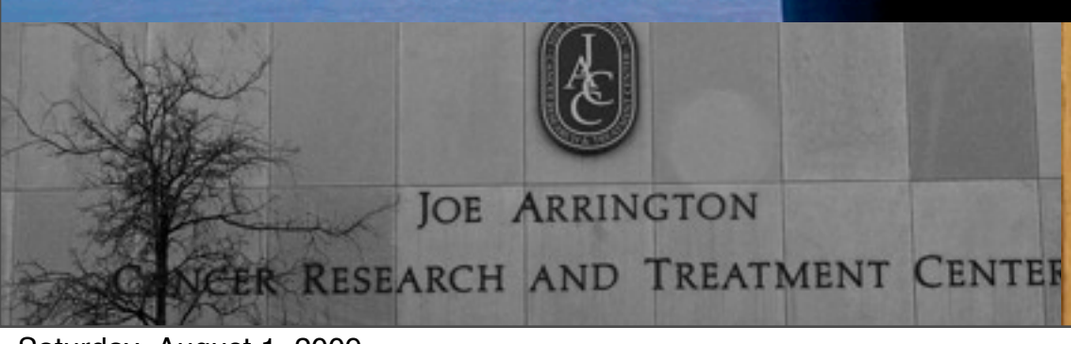
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